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110TH CONGRESS
2D SESSION

H. R. 6898

To promote the adoption and meaningful use of health information technology, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

SEPTEMBER 15, 2008

Mr. STARK (for himself, Ms. SCHWARTZ, Mr. MCDERMOTT, Mr. MCNULTY, Mr. LEVIN, Mr. EMANUEL, Mr. NEAL of Massachusetts, Mr. PASCRELL, and Mr. LEWIS of Georgia) introduced the following bill; which was referred to the Committee on Energy and Commerce, and in addition to the Committees on Ways and Means and Science and Technology, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

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A BILL

To promote the adoption and meaningful use of health information technology, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE; TABLE OF CONTENTS.

(a) SHORT TITLE.—This Act may be cited as the "Health-e Information Technology Act of 2008".

(b) TABLE OF CONTENTS.—The table of contents for this Act is as follows:

Sec. 1. Short title; table of contents.

TITLE I—PROMOTION OF HEALTH INFORMATION TECHNOLOGY

Subtitle A—Improving Health Care Quality, Safety, and Efficiency

Sec. 101. ONCHIT; standards development and adoption; health information technology resource center.

"TITLE XXX—HEALTH INFORMATION TECHNOLOGY AND QUALITY

"Sec. 3000. Definitions.

"Subtitle A—Promotion of Health Information Technology

"Sec. 3001. Office of the National Coordinator for Health Information Technology.
"Sec. 3002. HIT Advisory Committee.
"Sec. 3003. Process for adoption of recommended standards and guidance.
"Sec. 3004. Application and use of adopted standards by Federal agencies.
"Sec. 3005. Voluntary application and use of adopted standards by private entities.
"Sec. 3006. Health Information Technology Resource Center.
Sec. 102. Transitions.

Subtitle B—Application and Use of Adopted Health Information Technology Standards; Reports

Sec. 111. Coordination of Federal activities with adopted standards.
Sec. 112. Application to private entities.
Sec. 113. Annual reports.

TITLE II—TESTING OF HEALTH INFORMATION TECHNOLOGY

Sec. 201. National Institute for Standards and Technology testing.

TITLE III—INCENTIVES FOR ADOPTION OF HEALTH INFORMATION TECHNOLOGY

Subtitle A—Medicare Program

Sec. 301. Incentives for eligible professionals.
Sec. 302. Incentives for hospitals.
Sec. 303. Incentives for certain Medicare Advantage plans.

Subtitle B—Other Incentives for the Implementation and Use of Health Information Technology

Sec. 311. Grant, loan, and demonstration programs.

"Subtitle B—Incentives for the Use of Health Information Technology

"Sec. 3011. Grants and loans to facilitate the widespread adoption of qualified health information technology.
"Sec. 3012. Demonstration program to integrate information technology into clinical education.

TITLE IV—PRIVACY AND SECURITY PROVISIONS

Sec. 400. Definitions.

Subtitle A—Improved Privacy Provisions and Security Provisions

Sec. 401. Application of security provisions and penalties to business associates of covered entities; annual guidance on privacy and security provisions.
Sec. 402. Notification in the case of breach.
Sec. 403. Education on health information privacy and report on compliance.
Sec. 404. Application of penalties to business associates of covered entities for violations of privacy contract requirements.
Sec. 405. Restrictions on certain uses and disclosures and sales of health information; accounting of certain protected health information disclosures; access to certain information in electronic format.
Sec. 406. Limitations on certain activities as part of health care operations.
Sec. 407. Study and report on application of privacy and security requirements to non-HIPAA covered entities.
Sec. 408. Temporary breach notification requirement for vendors of personal health records and other non-HIPAA covered entities.
Sec. 409. Business associate contracts required for certain entities; other provisions related to business associate contracts.
Sec. 410. Guidance on implementation specification to de-identify protected health information.
Sec. 411. GAO report on treatment, payment, and health care operations uses and disclosures.
Sec. 412. Clarification of application of wrongful disclosures criminal penalties.
Sec. 413. Improved enforcement.
Sec. 414. Audits.
Sec. 415. Technical amendment.

Subtitle B—Chief Privacy Officer of ONCHIT; Standards and Guidance Recommendations Related to Privacy and Security

Sec. 421. Chief Privacy Officer of the Office of the National Coordinator .
Sec. 422. Additional standards and guidance recommendations related to privacy and security.

Subtitle C—Relationship to Other Laws; Regulatory References; Effective Date

Sec. 431. Relationship to other laws.
Sec. 432. Regulatory references.
Sec. 433. Effective date.

TITLE I—PROMOTION OF HEALTH INFORMATION TECHNOLOGY

Subtitle A—Improving Health Care Quality, Safety, and Efficiency

SEC. 101. ONCHIT; STANDARDS DEVELOPMENT AND ADOPTION; HEALTH INFORMATION TECHNOLOGY RESOURCE CENTER.

(a) IN GENERAL.—The Public Health Service Act (42 U.S.C. 201 et seq.) is amended by adding at the end the following:

"TITLE XXX—HEALTH INFORMATION TECHNOLOGY AND QUALITY

"SEC. 3000. DEFINITIONS.

"In this title:

"(1) ELECTRONIC HEALTH RECORD.—The term 'electronic health record' means an electronic record of health-related information on an individual that is created, managed, and consulted by authorized health care clinicians and staff of one or more organizations, that conforms to standards adopted under section 3003(a), and is made accessible electronically to other health care organizations and other authorized users.

"(2) HEALTH CARE PROVIDER.—The term 'health care provider' means a hospital, skilled nursing facility, nursing facility, home health entity, health care clinic, Federally qualified health center, group practice (as defined in section 1877(h)(4) of the Social Security Act), a pharmacist, a pharmacy, a laboratory, a physician (as defined in section 1861(r)) of the Social Security Act), a practitioner (as described in section 1842(b)(18)(C) of the Social Security Act), a provider operated by, or under contract with, the Indian Health Service or by an Indian tribe (as defined in the Indian Self-Determination and Education Assistance Act), tribal organization, or urban Indian organization (as defined in section 4 of the Indian Health Care Improvement Act), a rural health clinic, and any other category of facility or clinician determined appropriate by the Secretary.

"(3) HEALTH INFORMATION.—The term 'health information' has the meaning given such term in section 1171(4) of the Social Security Act.

"(4) HEALTH INFORMATION TECHNOLOGY.—The term 'health information technology' means hardware, software, integrated technologies and related licenses, intellectual property, upgrades, and

packaged solutions sold as services that are specifically designed for use by health care entities for the electronic creation, maintenance, or exchange of health information.

"(5) HEALTH PLAN.—The term 'health plan' has the meaning given such term in section 1171(5) of the Social Security Act.

"(6) HIT ADVISORY COMMITTEE.—The term 'HIT Advisory Committee' means such Committee established under section 3002(a).

"(7) INDIVIDUALLY IDENTIFIABLE HEALTH INFORMATION.—The term 'individually identifiable health information' has the meaning given such term in section 1171(6) of the Social Security Act.

"(8) LABORATORY.—The term 'laboratory' has the meaning given such term in section 353(a).

"(9) NATIONAL COORDINATOR.—The term 'National Coordinator' means the head of the Office of the National Coordinator for Health Information Technology established under section 3001(a).

"(10) PHARMACIST.—The term 'pharmacist' has the meaning given such term in section 804(2) of the Federal Food, Drug, and Cosmetic Act.

"(11) STATE.—The term 'State' means each of the several States, the District of Columbia, Puerto

Rico, the Virgin Islands, Guam, American Samoa, and the Northern Mariana Islands.

"Subtitle A—Promotion of Health Information Technology

"SEC. 3001. OFFICE OF THE NATIONAL COORDINATOR FOR HEALTH INFORMATION TECHNOLOGY.

"(a) ESTABLISHMENT.—There is established within the Department of Health and Human Services an Office of the National Coordinator for Health Information Technology (referred to in this section as the 'Office'). The Office shall be headed by a National Coordinator who shall be appointed by the Secretary and shall report directly to the Secretary.

"(b) PURPOSE.—The National Coordinator shall perform the duties under subsection (c) in a manner consistent with the development of a nationwide health information technology infrastructure that allows for the electronic use and exchange of information and that—

"(1) ensures that each patient's health information is secure and protected, in accordance with applicable law;

"(2) improves health care quality, reduces medical errors, and advances the delivery of patient-centered medical care;

"(3) reduces health care costs resulting from inefficiency, medical errors, inappropriate care, duplicative care, and incomplete information;

"(4) ensures that appropriate information to help guide medical decisions is available at the time and place of care;

"(5) ensures the inclusion of meaningful public input in such development of such infrastructure;

"(6) improves the coordination of care and information among hospitals, laboratories, physician offices, and other entities through an effective infrastructure for the secure and authorized exchange of health care information;

"(7) improves public health reporting and facilitates the early identification and rapid response to public health threats and emergencies, including bioterror events and infectious disease outbreaks;

"(8) facilitates health and clinical research and health care quality;

"(9) promotes prevention of chronic diseases;

"(10) promotes a more effective marketplace, greater competition, greater systems analysis, increased consumer choice, and improved outcomes in health care services; and

"(11) improves efforts to reduce health disparities.

"(c) DUTIES OF THE NATIONAL COORDINATOR.—

"(1) HIT POLICY COORDINATION.—The National Coordinator shall coordinate health information technology policy and programs within the Department and with those of other relevant executive branch agencies with a goal of avoiding duplication of efforts and of helping to ensure that each agency undertakes health information technology activities primarily within the areas of its greatest expertise and technical capability.

"(2) STANDARDS, GUIDANCE.—

"(A) DEVELOPMENT AND RECOMMENDATIONS OF STANDARDS AND GUIDANCE.—

"(i) IN GENERAL.—

"(I) INITIAL IMPLEMENTATION.—The National Coordinator shall, in consultation with the HIT Advisory Committee under section 3002 and consistent with the implementation of the strategic plan under paragraph (6), develop and recommend to the Secretary standards and guidance (which may include best

practices), as applicable, for each of the categories described in clauses (iii), (iv), and (v). In accordance with the previous sentence, the National Coordinator shall ensure that an initial set of appropriate standards is developed and recommended to the Secretary under this subclause by such time as to enable the Secretary to adopt such an initial set in accordance with section 3003(b).

"(II) BIENNIAL UPDATING.—Biennially thereafter the National Coordinator, in consultation with the HIT Advisory Committee, shall update such recommendations and make new recommendations as appropriate, including in response to a notification sent under section 3003(a)(2).

"(ii) COORDINATION AMONG CATEGORIES.—The National Coordinator shall coordinate the development, recommendations, and updating among the categories so described to take into account the inter-

dependence of standards and guidance among such categories.

"(iii) TECHNICAL INTEROPERABILITY CATEGORY.—

"(I) IN GENERAL.—The category described in this clause is the category for technical interoperability to provide for the electronic exchange and use of health information.

"(II) APPLICATION TO DIFFERENT LEVELS OF INTEROPERABILITY.—In developing recommendations respecting the category described in this clause, the National Coordinator shall initially use the different levels of interoperability (as described on pages 6 though 8 of GAO report 08–954 titled 'Electronic Health Records: DOD and VA Have Increased Sharing of Health Information, but More Work Remains' and provide for the development and recommendations of different standards and guidance for each of such different levels.

"(iv) PRIVACY AND SECURITY CATEGORY.—The category described in this clause is the category for privacy and security to ensure the secure exchange of protected health information, in accordance with title IV of the Health-e Information Technology Act of 2008 including the amendments made by such title.

"(v) CLINICAL AND QUALITY CATEGORY.—

"(I) IN GENERAL.—The category described in this clause is the category for clinical and quality functionalities of health information technology and strategies to enhance the use of such technology including for the following purposes:

"(aa) To improve the quality of health care, such as through the reduction of medical errors, using electronic provider order entry and clinical decision support systems.

"(bb) To facilitate patient-centered care, such as through

improved patient-provider communication through secure electronic messaging, and improved patient support.

"(cc) To reduce health disparities.

"(dd) To improve population health, such as through the use of registries and automated quality reporting and performance measures.

"(ee) To improve the continuity of care among health care settings.

"(II) REQUIREMENTS.—In developing recommendations respecting the category described in this clause, the National Coordinator shall ensure the following:

"(aa) Information is collected and transmitted in a manner that is reliable, accurate, and unambiguous and based on a uniform provider data set, including

a set of comprehensive data elements.

"(bb) Information is communicated in a manner to promote coordination of health care, applying appropriate data filtering for the situation.

"(cc) Practices optimize for continuous improvement, advancement of research and education, and population disease management.

"(dd) Sensitive protected health information may be segmented, with the goal of minimizing the reluctance of patients to seek care (or disclose information about a condition) because of privacy concerns involving sensitive protected health information, while maximizing patient safety and clinical utility of the information.

"(B) INCORPORATION OF CURRENT CCHIT CERTIFICATION CRITERIA.—In developing and

recommending standards and guidance under subparagraph (A), the National Coordinator shall, to the maximum extent appropriate, incorporate the ambulatory and inpatient functionality certification criteria that have been adopted by the Certification Commission for Health Information Technology as of the date of the enactment of this title. Nothing in this paragraph shall be construed as preventing the National Coordinator from incorporating into such recommendations such certification criteria as such Commission is in the process of adopting as of such date.

"(C) PROVIDER AND SETTING SPECIFIC.—Recommendations made under subparagraph (A) may be established in a provider-specific and setting-specific manner and in a manner such that they apply to a broad variety of providers, including physicians, hospitals, and other health care providers and to a broad variety of settings, including for health information technology systems that are hospital-based and for such systems that are office-based.

"(D) PILOT TESTING OF STANDARDS AND IMPLEMENTATION SPECIFICATIONS.—In the de-

velopment of standards under this paragraph, the National Coordinator, as appropriate, shall provide for the testing of such standards in collaboration with the National Institute for Standards and Technology under section 201 of the Health-e Information Technology Act of 2008.

"(E) CONSISTENCY WITH PRIVACY AND SECURITY REQUIREMENTS.—The standards recommended under this paragraph shall be consistent with applicable privacy and security standards and requirements adopted pursuant to section 1173 of the Social Security Act, to title IV of the Health-e Information Technology Act of 2008, or otherwise.

"(F) PUBLIC INPUT.—The National Coordinator shall conduct open public meetings and develop a process to allow for public comment on the recommendations made under this paragraph. Under such process comments shall be submitted in a timely manner after the date of publication of a recommendation under this paragraph.

"(G) PUBLICATION.—The Secretary shall provide for publication in the Federal Register

and the posting on the Internet website of the Office of the National Coordinator for Health Information Technology of all recommendations made by the National Coordinator under this paragraph.

"(3) CERTIFICATION.—The National Coordinator, in consultation with the Director of the National Institute of Standards and Technology and other relevant Federal agencies, shall develop a program (either directly or by contract) for the voluntary certification (and periodic recertification) of health information technology systems (and components of such systems) as being in compliance with all applicable standards (for each category described in paragraph (2)(A)) that are adopted under this subtitle. Such program shall include testing of the technology in accordance with section 201(b) of the Health-e Information Technology Act of 2008.

"(4) FEDERAL OPEN SOURCE HEALTH IT SYSTEM.—

"(A) IN GENERAL.—The National Coordinator shall provide for coordinating the development, routine updating, and provision of an open source health information technology system that is either new or based on an open

source health information technology system, such as VistA, that is in existence as of the date of the enactment of this title and that is in compliance with all applicable standards (for each category described in paragraph (2)(A)) that are adopted under this subtitle. The National Coordinator shall make such system publicly available for use, after appropriate pilot testing, as soon as practicable but not later than 9 months after the date of the adoption by the Secretary of the initial set of standards and guidance under section 3003(c).

"(B) CONSORTIUM.—In order to carry out subparagraph (A), the National Coordinator shall establish, not later than 6 months after the date of the enactment of this section, a consortium comprised of individuals with technical, clinical, and legal expertise open source health information technology. The Secretary, through agencies with the Department, shall provide assistance to the consortium in conducting its activities under this paragraph.

"(C) AUTHORIZATION TO CHARGE NOMINAL FEE.—The National Coordinator may impose a nominal fee for the adoption by a health

care provider of the health information technology system developed or approved under subparagraph (A). Such fee shall take into account the circumstances of smaller providers and providers located in rural or other medically underserved areas.

"(D) OPEN SOURCE DEFINED.—In this paragraph, the term 'open source' has the meaning given such term by the Open Source Initiative.

"(5) NATIONWIDE HEALTH INFORMATION NETWORK.—The National Coordinator shall facilitate the development and expansion of sub-national health information organizations and the coordination of such organizations in order to provide for the nationwide electronic exchange of health information among such organizations that ensures that appropriate information is available at the time and place of care and enables the aggregation of health information for research and public health purposes.

"(6) STRATEGIC PLAN.—

"(A) IN GENERAL.—Not later than 12 months after the date of the enactment of this title, the National Coordinator shall, in consultation with other appropriate Federal agen-

cies (including the National Institute of Standards and Technology), develop and maintain a strategic plan with specific objectives, milestones, and metrics for each strategic plan area described in subparagraph (B). The National Coordinator shall, in consultation with such other appropriate Federal agencies, annually update such strategic plan.

"(B) STRATEGIC PLAN AREAS REQUIRED.—The strategic plan areas include at least the following:

"(i) The establishment of recommendations for and development of standards and guidance for each category under paragraph (2)(A), including recommendations described in section 422 of the Health-e Information Technology Act of 2008, and the adoption of standards so recommended, including the process of updating of such standards and guidance.

"(ii) The development of the certification program under paragraph (3) and the establishment and maintenance of a list of health information technology systems (and components of such systems)

that have been certified under such program.

"(iii) The development of a Federal open source health IT system in accordance with paragraph (4).

"(iv) The widespread utilization of electronic health records in the United States and the establishment of a nationwide health information network described in paragraph (5).

"(v) Specifying a framework for the coordination and flow of recommendations and policies under this subtitle among the Secretary, the National Coordinator, the HIT Policy Committee, health information exchanges, and other relevant entities.

"(vi) Methods to foster the public understanding of health information technology and related privacy and security laws.

"(vii) The availability of technical assistance and training for health care providers in the implementation and utilization of health information technology systems.

"(C) COLLABORATION.—The strategic plan shall be developed and updated through collaboration of public and private interests.

"(D) MEASURABLE OUTCOME GOALS.—The strategic plan shall include measurable outcome goals including timeframes for such goals.

"(E) PUBLICATION.—The National Coordinator shall publish the strategic plan, including all updates.

"(7) IMPLEMENTATION REPORTS.—Not later than 12 months after the date of publication of the strategic plan under paragraph (6) and annually thereafter, the National Coordinator shall submit to the Secretary a report that identifies the progress achieved with respect to the objectives, milestones, and metrics identified in such strategic plan for each strategic plan area described in paragraph (6)(B).

"(8) ASSESSMENT OF IMPACT OF HIT ON COMMUNITIES WITH HEALTH DISPARITIES AND UNINSURED, UNDERINSURED, AND MEDICALLY UNDERSERVED AREAS.—The National Coordinator shall assess and publish the impact of health information technology in communities with health disparities and in areas that serve uninsured, underinsured, and medically underserved individuals (including

urban and rural areas) and identify practices to increase the adoption of such technology by health care providers in such communities.

"(9) WEBSITE.—The National Coordinator shall maintain and frequently update an Internet website on which there is posted information that includes the following:

"(A) Recommendations made by the National Coordinator under paragraph (2)(A).

"(B) The standards and guidance adopted by the Secretary under section 3003(a).

"(C) Sources of Federal grant funds and technical assistance that are available to facilitate the purchase of, or enhance the utilization of, health information technology systems.

"(D) The reports prepared by the National Coordinator under paragraph (7).

"(E) The assessment by the National Coordinator under paragraph (8).

"(d) STAFF.—

"(1) IN GENERAL.—The National Coordinator may appoint personnel to the Office as the National Coordinator considers appropriate. Such personnel shall have the requisite skills needed to develop and make recommendations in each of the categories de-

scribed in clauses (iii), (iv), and (v) of subsection (c)(2)(A).

"(2) DETAIL OF FEDERAL EMPLOYEES.—

"(A) IN GENERAL.—Upon the request of the National Coordinator, the head of any Federal agency is authorized to detail, with or without reimbursement from the Office, any of the personnel of such agency to the Office to assist it in carrying out its duties under this section.

"(B) EFFECT OF DETAIL.—Any detail of personnel under subparagraph (A) shall—

"(i) not interrupt or otherwise affect the civil service status or privileges of the Federal employee; and

"(ii) be in addition to any other staff of the Department employed by the National Coordinator.

"(C) ACCEPTANCE OF DETAILEES.—Notwithstanding any other provision of law, the Office may accept detailed personnel from other Federal agencies without regard to whether the agency described under subparagraph (A) is reimbursed.

"(3) TEMPORARY AND INTERMITTENT SERVICES.—The National Coordinator may procure tem-

porary and intermittent services under section 3109(b) of title 5, United States Code to the extent that such services cannot adequately be provided by any personnel appointed or detailed under paragraph (1) or (2), respectively.

"(e) FUNDING.—

"(1) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to carry out this section such sums as may be necessary for each of the fiscal years 2009 through 2013.

"(2) DHHS AGENCY CONTRIBUTIONS.—In addition to amounts authorized under paragraph (1), for purposes of carrying out this section, for each of the fiscal years 2009 through 2013 there shall be transferred to the National Coordinator from the amount appropriated for the fiscal year to each agency within the Department an amount that is equal to 1 percent of the amount appropriated to the agency for the fiscal year to carry out health information technology activities.

"(3) OPEN SOURCE PRODUCT LICENSING FEE.—In addition to amounts authorized under paragraph (1) and transferred under paragraph (2), any fees collected under subsection (c)(4)(B) shall be

available to the National Coordinator for purposes of carrying out this section.

"SEC. 3002. HIT ADVISORY COMMITTEE.

"(a) ESTABLISHMENT.—There is established a HIT Advisory Committee to make recommendations to and advise the National Coordinator with respect to all of the duties of the National Coordinator described in section 3001(c).

"(b) ADDITIONAL DUTIES.—

"(1) FORUM.—The HIT Advisory Committee shall serve as a forum for broad stakeholder input with specific expertise necessary to advise the National Coordinator for purposes of carrying out the duties of the National Coordinator described in section 3001(c), including expertise related to the categories described in paragraph (2)(A) of such section.

"(2) WEBSITE.—The HIT Advisory Committee shall develop and maintain an Internet website on which there is posted information that includes the following:

"(A) Established governance rules.

"(B) A business plan.

"(C) Meeting notices at least 14 days prior to each meeting.

"(D) Meeting agendas at least 7 days prior to each meeting.

"(E) Meeting materials at least 3 days prior to each meeting.

"(c) MEMBERSHIP.—

"(1) APPOINTMENTS.—The HIT Advisory Committee shall be composed of members to be appointed as follows:

"(A) Such members as shall be appointed by the Secretary, from the Department of Health and Human Services as representatives of agencies within the Department, including from the Agency for Healthcare Research and Quality, the Centers for Disease Control and Prevention, the Centers of Medicare & Medicaid Services, the Health Resources and Services Administration, and the Indian Health Service.

"(B) 1 member shall be appointed by the majority leader of the Senate.

"(C) 1 member shall be appointed by the minority leader of the Senate.

"(D) 1 member shall be appointed by the Speaker of the House of Representatives.

"(E) 1 member shall be appointed by the minority leader of the House of Representatives.

"(F) Such other members as shall be appointed by the President as representatives of other relevant Federal agencies, such as the Department of Veterans Affairs, the National Institute of Standards and Technology, and the Department of Defense.

"(G) 12 members shall be appointed by the Comptroller General of the United States of whom—

"(i) 1 member shall be an advocate for patients or consumers;

"(ii) 2 members shall represent health care providers, one of which shall be a physician;

"(iii) 1 member shall be from a labor organization representing health care workers;

"(iv) 1 member shall have expertise in privacy and security;

"(v) 1 member shall have expertise in improving the health of vulnerable populations;

"(vi) 1 member shall be from the health research community;

"(vii) 1 member shall represent health plans or other third-party payers;

"(viii) 1 member shall represent information technology vendors;

"(ix) 1 member shall represent purchasers or employers;

"(x) 1 member shall have expertise in health care quality measurement and reporting; and

"(xi) 1 member shall have expertise in open source health information technology systems.

In no case may the total number of members appointed under subparagraphs (A) and (F) exceed 10.

"(2) NATIONAL COORDINATOR.—The National Coordinator shall be a member of the HIT Advisory Committee and act as a liaison between the Committee and agencies of the Federal Government.

"(3) CHAIRPERSON AND VICE CHAIRPERSON.—The HIT Advisory Committee shall designate 1 member to serve as the chairperson and 1 member to serve as the vice chairperson of the HIT Advisory

Committee, such that one is a representative of the public sector and one is a representative from the private sector.

"(4) PARTICIPATION.—The members of the HIT Advisory Committee appointed under paragraph (1) shall represent a balance among various sectors of the health care system so that no single sector unduly influences the recommendations of such Committee.

"(5) AUTHORIZED USE OF TASK FORCES AND WORK GROUPS.—The National Coordinator, in consultation with the chairperson and vice chairperson of the HIT Advisory Committee, may convene task forces or working groups as necessary to carry out the duties of the Committee.

"(6) COMPENSATION.—Subject to the availability of appropriations, while serving on the business of the HIT Advisory Committee (including traveltime), a member of the Committee who is not a Federal employee shall be entitled to compensation at the per diem equivalent of the rate provided for level IV of the Executive Schedule under section 5315 of title 5, United States Code; and while so serving away from home and the member's regular place of business, a member may be allowed travel

expenses, as authorized by the Chairman of the Committee.

"(7) TERMS.—

"(A) IN GENERAL.—The terms of members of the HIT Advisory Committee appointed under paragraph (1) shall be 3 years except that the Comptroller General of the United States shall designate staggered terms for the members first appointed under paragraph (1)(G).

"(B) VACANCIES.—Any member appointed to fill a vacancy in the membership of the HIT Advisory Committee that occurs prior to the expiration of the term for which the member's predecessor was appointed shall be appointed only for the remainder of that term. A member may serve after the expiration of that member's term until a successor has been appointed. A vacancy in the HIT Advisory Committee shall be filled in the manner in which the original appointment was made.

"(8) OUTSIDE INVOLVEMENT.—The HIT Advisory Committee shall ensure an adequate opportunity for the participation in activities of the Committee of outside advisors, including individuals with

expertise in the development of policies for the electronic exchange and use of health information, including in the areas of health information privacy and security.

"(9) QUORUM.—Ten members of the HIT Advisory Committee shall constitute a quorum for purposes of voting, but a lesser number of members may meet and hold hearings.

"(d) APPLICATION OF FACA.—The Federal Advisory Committee Act (5 U.S.C. App.), other than section 14 of such Act, shall apply to the HIT Advisory Committee.

"(e) PUBLICATION.—The Secretary shall provide for publication in the Federal Register and the posting on the Internet website of the Office of the National Coordinator for Health Information Technology of all policy recommendations made by the HIT Advisory Committee under this section.

"SEC. 3003. PROCESS FOR ADOPTION OF RECOMMENDED STANDARDS AND GUIDANCE.

"(a) IN GENERAL.—

"(1) STANDARDS.—Not later than 9 months after the date of receipt of a recommendation under section 3001(c)(2) from the National Coordinator for any grouping of standards for purposes of certifying health information technology under the cer-

tification program under section 3001(c)(3), the Secretary shall, through a rulemaking process and after consideration of public comments, determine whether or not to adopt such grouping of standards.

"(2) GUIDANCE.—Not later than 9 months after the date of receipt of a recommendation under section 3001(c)(2) from the National Coordinator for any guidance, the Secretary shall, through the applicable administrative process that includes public notice in the Federal Register and opportunity for public comment, determine whether or not to adopt such guidance.

"(b) INITIAL STANDARDS.—Not later than September 30, 2011, the Secretary shall, through a rulemaking process and after consideration of public comments, adopt the initial set of standards recommended from the National Coordinator pursuant to the second sentence under section 3001(c)(2). Such initial set of standards shall include, at a minimum, technical standards for de-identifying health information and for immutable audit trails.

"(c) PUBLICATION.—Not later than 30 days after the Secretary makes a determination under subsection (a), the Secretary shall provide for publication in the Federal Register, and on the Internet website maintained by the Na-

tional Coordinator in accordance with section 3001(c)(9), of such determination.

"SEC. 3004. APPLICATION AND USE OF ADOPTED STANDARDS BY FEDERAL AGENCIES.

"For requirements relating to the application and use by Federal agencies of the standards adopted under section 3003(a), see section 111 of the Health-e Information Technology Act of 2008.

"SEC. 3005. VOLUNTARY APPLICATION AND USE OF ADOPTED STANDARDS BY PRIVATE ENTITIES.

"(a) IN GENERAL.—Except as provided under section 112 of the Health-e Information Technology Act of 2008, any standard adopted under section 3003(a) shall be voluntary with respect to private entities.

"(b) RULE OF CONSTRUCTION.—Nothing in this subtitle shall be construed to require that a private entity that enters into a contract with the Federal Government apply or use the standards adopted under section 3003(a) with respect to activities not related to the contract. The previous sentence shall not affect any other provision of law, such as part C of title XI of the Social Security Act, title III of the Health-e Information Technology Act of 2008, or regulations promulgated to carry out section 264(c) of the Health Insurance Portability and Accountability Act

of 1996, that requires the application or use of such a standard.

"SEC. 3006. HEALTH INFORMATION TECHNOLOGY RESOURCE CENTER.

"(a) DEVELOPMENT.—

"(1) IN GENERAL.—The National Coordinator shall develop a Health Information Technology Resource Center to provide technical assistance and develop best practices to support and accelerate efforts to adopt, implement, and effectively use health information technology that allows for the electronic exchange and use of information in compliance with standards and any guidance adopted under section 3003(a), including for purposes of each of the categories described in such section 3001(c)(2).

"(2) PURPOSES.—The purpose of the Center is to—

"(A) provide a forum for the exchange of knowledge and experience;

"(B) accelerate the transfer of lessons learned from existing public and private sector initiatives, including those currently receiving Federal financial support;

"(C) assemble, analyze, and widely disseminate evidence and experience related to the

adoption, implementation, and effective use of health information technology that allows for the electronic exchange and use of information;

"(D) provide technical assistance for the establishment and evaluation of regional and local health information networks to facilitate the electronic exchange of information across health care settings and improve the quality of health care;

"(E) provide technical assistance for the development and dissemination of solutions to barriers to the exchange of electronic health information;

"(F) learn about effective strategies to adopt and utilize health information technology in medically underserved communities;

"(G) conduct other activities identified by the States, local or regional health information networks, or health care stakeholders as a focus for developing and sharing best practices; and

"(H) provide technical assistance to promote adoption and utilization of health information technology by health care providers, including in medically underserved communities.

"(b) TECHNICAL ASSISTANCE TELEPHONE NUMBER OR WEBSITE.—The National Coordinator shall establish a toll-free telephone number or Internet website to provide health care providers with a single point of contact to—

"(1) learn about Federal grants and technical assistance services related to the electronic exchange and use of health information;

"(2) learn about standards adopted under section 3003(a);

"(3) learn about regional and local health information networks for assistance with health information technology; and

"(4) disseminate additional information determined by the National Coordinator.".

SEC. 102. TRANSITIONS.

(a) ONCHIT.—To the extent consistent with section 3001 of the Public Health Service Act, as added by section 101, all functions, personnel, assets, liabilities, and administrative actions applicable to the National Coordinator for Health Information Technology appointed under Executive Order 13335 or the Office of such National Coordinator on the date before the date of the enactment of this Act shall be transferred to the National Coordinator appointed under section 3001(a) of such Act and the Office

of such National Coordinator as of the date of the enactment of this Act.

(b) AHIC.—To the extent consistent with section 3002 of the Public Health Service Act, as added by section 101, all functions, personnel, assets, and liabilities applicable to the American Health Information Community created in response to Executive Order 13335 as of the day before the date of the enactment of this Act shall be transferred to the HIT Advisory Committee, established under section 3002(a)of such Act, as appropriate, as of the date of the enactment of this Act.

(c) RULES OF CONSTRUCTION.—

(1) ONCHIT.—Nothing in section 3001 of the Public Health Service Act, as added by section 101, or subsection (a) shall be construed as requiring the creation of a new entity to the extent that the Office of the National Coordinator for Health Information Technology established pursuant to Executive Order 13335 is consistent with the provisions of such section 3001.

(2) AHIC.—Nothing in section 3002 of the Public Health Service Act, as added by section 101, or subsection (b) shall be construed as requiring the creation of a new entity to the extent that the American Health Information Community created in re-

sponse to Executive Order 13335 is consistent with the provisions of such section 3002.

Subtitle B—Application and Use of Adopted Health Information Technology Standards; Reports

SEC. 111. COORDINATION OF FEDERAL ACTIVITIES WITH ADOPTED STANDARDS.

(a) SPENDING ON HEALTH INFORMATION TECHNOLOGY SYSTEMS.—As each agency (as defined in the Executive Order issued on August 22, 2006, relating to promoting quality and efficient health care in Federal government administered or sponsored health care programs) implements, acquires, or upgrades health information technology systems used for the direct exchange of individually identifiable health information between agencies and with non-Federal entities, it shall utilize, where available, health information technology systems and products that meet standards adopted under section 3003(a) of the Public Health Service Act, as added by section 101.

(b) FEDERAL INFORMATION COLLECTION ACTIVITIES.—With respect to a standard adopted under section 3003(a) of the Public Health Service Act, as added by section 101, the President shall take measures to ensure that Federal activities involving the broad collection and submission of health information are consistent with such

standard within three years after the date of such adoption.

(c) APPLICATION OF DEFINITIONS.—The definitions contained in section 3000 of the Public Health Service Act, as added by section 101, shall apply for purposes of this part.

SEC. 112. APPLICATION TO PRIVATE ENTITIES.

Each agency (as defined in such Executive Order issued on August 22, 2006, relating to promoting quality and efficient health care in Federal government administered or sponsored health care programs) shall require in contracts or agreements with health care providers, health plans, or health insurance issuers that as each provider, plan, or issuer implements, acquires, or upgrades health information technology systems, it shall utilize, where available, health information technology systems and products that meet standards adopted under section 3003(a) of the Public Health Service Act, as added by section 101.

SEC. 113. ANNUAL REPORTS.

Not later than 2 years after the date of the enactment of this Act and annually thereafter, the Secretary of Health and Human Services shall submit to the Committee on Finance, the Committee on Health, Education, Labor, and Pensions and the Committee on Commerce, Science, and Transportation of the Senate and the Com-

mittee on Ways and Means, the Committee on Energy and Commerce, and the Committee on Science and Technology of the House of Representatives a report that—

(1) describes the specific actions that have been taken by the Federal Government and private entities to facilitate the adoption of a nationwide system for the electronic use and exchange of health information, including information from the implementation reports submitted under section 3001(c)(7) of the Public Health Service Act, as added by section 101;

(2) describes barriers to the adoption of such a nationwide system; and

(3) contains recommendations to achieve full implementation of such a nationwide system.

TITLE II—TESTING OF HEALTH INFORMATION TECHNOLOGY

SEC. 201. NATIONAL INSTITUTE FOR STANDARDS AND TECHNOLOGY TESTING.

(a) PILOT TESTING OF STANDARDS AND IMPLEMENTATION SPECIFICATIONS.—In coordination with the Office of the National Coordinator of Health Information Technology established under section 3001 of the Public Health Service Act, as added by section 101, with respect to the development of standards under such section, the

Director of the National Institute for Standards and Technology shall test such standards in order to assure the efficient implementation and use of such standards.

(b) VOLUNTARY TESTING PROGRAM.—In coordination with the Office of the National Coordinator of Health Information Technology established under section 3001 of the Public Health Service Act, as added by section 101, with respect to the development of standards under such section, the Director of the National Institute of Standards and Technology shall support the establishment of a conformance testing infrastructure, including the development of technical test beds. The development of this conformance testing infrastructure may include a program to accredit independent, non-Federal laboratories to perform testing.

TITLE III—INCENTIVES FOR ADOPTION OF HEALTH INFORMATION TECHNOLOGY

Subtitle A—Medicare Program

SEC. 301. INCENTIVES FOR ELIGIBLE PROFESSIONALS.

(a) INCENTIVE PAYMENTS.—Section 1848 of the Social Security Act (42 U.S.C. 1395w–4) is amended by adding at the end the following new subsection:

"(o) INCENTIVES FOR ADOPTION AND MEANINGFUL USE OF CERTIFIED HEALTH INFORMATION TECHNOLOGY SYSTEM.—

"(1) INCENTIVE PAYMENTS.—

"(A) IN GENERAL.—Subject to subparagraphs (B), (C), and (D), with respect to covered professional services furnished by an eligible professional during a reporting period during the first calendar year beginning after the date specified under subparagraph (B)(iv) (or, if sooner, 2013) or any subsequent year (before 2017), if the eligible professional is a meaningful HIT user for the reporting period (as determined under paragraph (2), in addition to the amount otherwise paid under this part, there also shall be paid to the eligible professional (or to an employer or facility in the cases described in clause (A) of section 1842(b)(6)) or, in the case of a group practice under paragraph (2)(D), to the group practice, from the Federal Supplementary Medical Insurance Trust Fund established under section 1841 an amount equal to 75 percent of the Secretary's estimate (based on claims submitted not later than 2 months after the end of the reporting period) of the al-

lowed charges under this part for all such covered professional services furnished by the eligible professional (or, in the case of a group practice under paragraph (2)(D), by the group practice) during the reporting period.

"(B) LIMITATIONS ON AMOUNTS OF INCENTIVE PAYMENTS.—

"(i) IN GENERAL.—In no case shall the amount of the incentive payment provided under this paragraph exceed the applicable amount specified in clause (ii) with respect to any eligible professional.

"(ii) AMOUNT.—Subject to clauses (iii) and (iv), the applicable amount specified in this clause is as follows:

"(I) For the first calendar year beginning after the date specified in clause (iv) or, if sooner, for 2013, $15,000.

"(II) For the calendar year following the year specified in subclause (I), $12,000.

"(III) For the calendar year following the year specified in subclause (II), $8,000.

"(IV) For the calendar year following the year specified in subclause (III), $4,000.

"(V) For the calendar year following the year specified in subclause (IV), $2,000.

"(iii) PRO-RATION FOR PARTIAL YEAR PROFESSIONALS.—In the case of an eligible professional who is a meaningful HIT user for only a portion of a reporting period for reasons such as the professional did not provide services for which payment is made under this part for the entire period or the professional initiated the use of health information technology during the period, the Secretary may pro-rate the applicable amount specified under clause (ii) to reflect the portion of the period during which the professional was a meaningful HIT user.

"(iv) DATE SPECIFIED.—The date specified in this subclause is the date on which the open source health information technology system under section

3001(c)(4) of the Public Health Service Act is first made publicly available.

"(C) NON-APPLICATION TO HOSPITAL-BASED ELIGIBLE PROFESSIONALS.—

"(i) IN GENERAL.—No payment may be made under subparagraph (A) in the case of hospital-based eligible professionals.

"(ii) HOSPITAL-BASED ELIGIBLE PROFESSIONAL.—For purposes of clause (i), the term 'hospital-based eligible professional' means an eligible professional, such as a pathologist or anesthesiologist, who furnishes items and services principally in a hospital setting and through the use of the facilities and equipment, including computer equipment, of the hospital.

"(D) FORM OF PAYMENT.—The payment under this subsection for a reporting period may be in the form of a single consolidated payment or in the form of such periodic installments as the Secretary may specify.

"(2) MEANINGFUL HIT USER.—

"(A) IN GENERAL.—For purposes of paragraph (1), an eligible professional shall be treated as a meaningful HIT user for a report-

ing period for a year if the eligible professional demonstrates to the satisfaction of the Secretary that the professional is meaningfully using a certified health information technology system during the reporting period, as demonstrated in accordance with applicable measures established under subparagraph (B).

"(B) MEASURES FOR MEANINGFUL USE.—The Secretary shall establish measures under which an eligible professional may demonstrate meaningful use of a certified health information technology system for a reporting period. Such measures may include—

"(i) self-certification of operational use of such a system;

"(ii) the submission (or ability to submit), in a form and manner specified by the Secretary, of such information on clinical measures and data (that does not include individually identifiable health information) from such system that indicates a meaningful utilization of such a system during the period; and

"(iii) such other means as the Secretary may specify.

The Secretary may establish and apply different measures based on the stage of implementation or adoption of the certified health information technology system involved.

"(C) USE OF PART D DATA.—Notwithstanding sections 1860D–15(d)(2)(B) and 1860D–15(f)(2), the Secretary may use data regarding drug claims submitted for purposes of section 1860D–15 that are necessary for purposes of subparagraph (B)(ii).

"(D) SATISFACTORY MEASURES FOR GROUP PRACTICES.—

"(i) IN GENERAL.—Not later than January 1, 2013, the Secretary shall provide for a method of applying the measures established under subparagraph (B) or revised under subparagraph (F) to eligible professionals in a group practice (as defined by the Secretary).

"(ii) STATISTICAL SAMPLING MODEL.—In the case that the Secretary provides for a method under clause (i), the method may provide for the use of a statistical sampling model to submit data on measures, such as the model used under

the Physician Group Practice demonstration project under section 1866A.

"(iii) NO DOUBLE PAYMENTS.—Payments for a reporting period to a group practice under this paragraph by reason of the method under clause (i) shall be in lieu of the payments that would otherwise be made under this paragraph to eligible professionals in the group practice for being a meaningful HIT user during such period.

"(E) AUTHORITY TO REVISE MEASURES.—The Secretary may periodically revise the measures established under subparagraph (B) with respect to demonstrating meaningful use of a certified health information technology system.

"(3) APPLICATION.—

"(A) PHYSICIAN REPORTING SYSTEM RULES.—Paragraphs (5), (6),and (8) of subsection (k) shall apply for purposes of this subsection in the same manner as they apply for purposes of such subsection.

"(B) COORDINATION WITH OTHER BONUS PAYMENTS.—The provisions of this subsection shall not be taken into account in applying subsections (m) and (u) of section 1833 and any

payment under such subsections shall not be taken into account in computing allowable charges under this subsection.

"(C) LIMITATIONS ON REVIEW.—There shall be no administrative or judicial review under 1869, section 1878, or otherwise of—

"(i) the determination of measures applicable to services furnished by eligible professionals under this subsection;

"(ii) the determination of a meaningful HIT user under paragraph (2)(A), a limitation under paragraph (1)(B), and the exception under subsection (a)(7)(B); and

"(iii) the determination of any incentive payment under this subsection and the payment adjustment under subsection (a)(7)(A).

"(D) POSTING ON WEBSITE.—The Secretary shall post on the Internet website of the Centers for Medicare & Medicaid Services, in an easily understandable format, a list of the names, business addresses, and business phone numbers of the eligible professionals (or, in the case of reporting under paragraph (2)(D), the

group practices) who are meaningful HIT users.

"(4) DEFINITIONS.—For purposes of this subsection:

"(A) CERTIFIED HEALTH INFORMATION TECHNOLOGY SYSTEM.—The term 'certified health information technology system' means, with respect to an eligible professional and a reporting period for a year, a health information technology system (as defined in section 3000 of the Public Health Service Act) that has a current certification under section 3001(c)(3) of such Act as satisfying all interoperability standards, privacy and security standards, and clinical and quality functions adopted under section 3003(a) of such Act that are applicable to the eligible professional.

"(B) COVERED PROFESSIONAL SERVICES.—The term 'covered professional services' has the meaning given such term in subsection (k)(3).

"(C) ELIGIBLE PROFESSIONAL.—The term 'eligible professional' means a physician, as defined in section 1861(r)(1).

"(D) REPORTING PERIOD.—The term 'reporting period' means any period, with respect to a calendar year, as specified by the Secretary.".

(b) INCENTIVE PAYMENT ADJUSTMENT.—Section 1848(a) of the Social Security Act (42 U.S.C. 1395w–4(a)) is amended by adding at the end the following new paragraph:

"(7) INCENTIVES FOR MEANINGFUL USE OF HEALTH INFORMATION TECHNOLOGY SYSTEMS.—

"(A) ADJUSTMENT.—

"(i) IN GENERAL.—Subject to subparagraph (B), with respect to covered professional services furnished by an eligible professional during 2016 or any subsequent year, if the eligible professional is not a meaningful HIT user for a reporting period for the year (as determined under subsection (o)(2)), the fee schedule amount for such services furnished by such professional during the year (including the fee schedule amount for purposes of determining a payment based on such amount) shall be equal to the applicable percent of the fee schedule amount that would other-

wise apply to such services under this subsection (determined after application of paragraph (3) but without regard to this paragraph).

"(ii) APPLICABLE PERCENT.—For purposes of clause (i), the term 'applicable percent' means—

"(I) for 2016, 99 percent;

"(II) for 2017, 98.5 percent;

"(III) for 2018, 98 percent;

"(IV) for 2019, 97.5 percent; and

"(V) for 2020 and each subsequent year, 97 percent.

"(B) SIGNIFICANT HARDSHIP EXCEPTION.—The Secretary may, on a case-by-case basis, exempt an eligible professional from the application of the payment adjustment under subparagraph (A) if the Secretary determines, subject to annual renewal, that compliance with the requirement for being a meaningful HIT user would result in a significant hardship, such as in the case of an eligible professional who practices in a rural area without sufficient Internet access. In no case may an eligible pro-

fessional be granted an exemption under this subparagraph for more than 5 years.

"(C) APPLICATION OF PHYSICIAN REPORTING SYSTEM RULES.—Paragraphs (5), (6), and (8) of subsection (k) shall apply for purposes of this paragraph in the same manner as they apply for purposes of such subsection.

"(D) NON-APPLICATION TO HOSPITAL-BASED ELIGIBLE PROFESSIONALS.—No payment adjustment may be made under subparagraph (A) in the case of hospital-based eligible professionals (as defined in subsection (o)(1)(C)(ii)).

"(E) DEFINITIONS.—For purposes of this paragraph:

"(i) COVERED PROFESSIONAL SERVICES.—The term 'covered professional services' has the meaning given such term in subsection (k)(3).

"(ii) ELIGIBLE PROFESSIONAL.—The term 'eligible professional' means a physician, as defined in section 1861(r)(1).

"(iii) REPORTING PERIOD.—The term 'reporting period' means, with respect to a year, a period specified by the Secretary.".

(c) CONFORMING AMENDMENTS TO E-PRESCRIBING.—

(1) Section 1848(a)(5)(A)(ii)(III) of the Social Security Act (42 U.S.C. 1395w–4(a)(5)(A)(ii)(III)) is amended by striking "and each subsequent year" and inserting "and 2015".

(2) Section 1848(m)(2) of the Social Security Act (42 U.S.C. 1395w–4(m)(2)) is amended—

(A) in subparagraph (A), by striking "For 2009" and inserting "Subject to subparagraph (D), for 2009"; and

(B) by adding at the end the following new subparagraph:

"(D) LIMITATION WITH RESPECT TO HEALTH INFORMATION TECHNOLOGY INCENTIVE PAYMENTS.—The provisions of this paragraph shall not apply to an eligible professional (or, in the case of a group practice under paragraph (3)(C), to the group practice) if, for the reporting period the eligible professional (or group practice) receives an incentive payment under subsection (o)(1)(A) with respect to a certified health information system (as defined in subsection (o)(4)(A)) that has the capability of electronic prescribing.".

(d) GAO STUDY AND REPORT.—

(1) STUDY.—The Comptroller General of the United States shall conduct a study to determine the extent to which and manner in which payment incentives (such as under title XVIII or XIX of the Social Security Act) and other funding for purposes of implementing and using health information technology should be made available to health care providers who are receiving minimal or no payment incentives or other funding under this Act, under title XVIII or XIX of the Social Security Act, or otherwise, for such purposes. Such study shall include an examination of—

(A) the adoption rates of certified health information technology systems by such health care providers;

(B) the clinical utility of such systems by such health care providers;

(C) whether the services furnished by such health care providers are appropriate for or would benefit from the use of such systems;

(D) the extent to which such health care providers work in settings that might otherwise receive an incentive payment or other funding

under this Act, title XVIII or XIX of the Social Security Act, or otherwise;

(E) the potential costs and the potential benefits of making payment incentives and other funding available to such health care providers; and

(F) any other issues the Comptroller General deems to be appropriate.

(2) REPORT.—Not later than June 30, 2010, the Comptroller General shall submit to Congress a report on the findings and conclusions of the study conducted under paragraph (1).

SEC. 302. INCENTIVES FOR HOSPITALS.

(a) INCENTIVE PAYMENT.—Section 1886 of the Social Security Act (42 U.S.C. 1395ww) is amended by adding at the end the following new subsection:

"(o) INCENTIVES FOR ADOPTION AND MEANINGFUL USE OF CERTIFIED HEALTH INFORMATION TECHNOLOGY SYSTEMS.—

"(1) IN GENERAL.—Subject to the succeeding provisions of this subsection, with respect to inpatient hospital services furnished by an eligible hospital during the first fiscal year beginning after the date specified in paragraph (6) (or, if sooner, fiscal year 2013) or any subsequent fiscal year (before fis-

cal year 2017), if the eligible hospital is a meaningful HIT user for the fiscal year (as determined under paragraph (3)), in addition to the amount otherwise paid under this section, there also shall be paid to the eligible hospital, from the Federal Hospital Insurance Trust Fund established under section 1817, an amount equal to the applicable amount specified in paragraph (2)(A) for such fiscal year.

"(2) PAYMENT AMOUNT.—

"(A) IN GENERAL.—Subject to subparagraph (F), the applicable amount specified in this subparagraph for an eligible hospital for a fiscal year is equal to the product of the following:

"(i) INITIAL AMOUNT.—The sum of—

"(I) the base amount specified in subparagraph (B); plus

"(II) the discharge related amount specified in subparagraph (C) for a period selected by the Secretary with respect to such fiscal year.

"(ii) MEDICARE SHARE.—The Medicare share as specified in subparagraph (D) for the hospital for a period selected

by the Secretary with respect to such fiscal year.

"(iii) TRANSITION FACTOR.—The transition factor specified in subparagraph (E) for the fiscal year.

"(B) BASE AMOUNT.—The base amount specified in this subparagraph is $1,000,000.

"(C) DISCHARGE RELATED AMOUNT.—The discharge related amount specified in this subparagraph for a period shall be determined as the sum of the amount, based upon total discharges (regardless of any source of payment) for the period, for each discharge up to the 13,800th discharge as follows:

"(i) For the 1150th through the 9,200nd discharge, $200.

"(ii) For the 9,201st through the 13,800th discharge, 50 percent of the amount specified in clause (i).

"(D) MEDICARE SHARE.—The Medicare share specified under this subparagraph for a hospital for a period is equal to the fraction—

"(i) the numerator of which is the sum (for the period and with respect to the hospital) of—

"(I) the number of inpatient-bed-days (as established by the Secretary) which are attributable to individuals with respect to whom payment may be made under part A; and

"(II) the number of inpatient-bed-days (as so established) which are attributable to individuals who are enrolled under a risk-sharing contract with an eligible organization under section 1876 and who are entitled to part A or with a Medicare Advantage organization under part C; and

"(ii) the denominator of which is the product of—

"(I) the total number of inpatient-bed-days with respect to the hospital during the period; and

"(II) the total amount of the hospital's charges during the period, not including any charges that are attributable to charity care (as such term is used for purposes of hospital cost reporting under this title), divided by

the total amount of the hospital's charges during the period.

"(E) TRANSITION FACTOR SPECIFIED.—The transition factor specified in this subparagraph is as follows:

"(i) For the first fiscal year beginning after the date specified in paragraph (6) (or, of sooner, fiscal year 2013), 1.

"(ii) For the fiscal year following the fiscal year specified in clause (i), ¾.

"(iii) For the fiscal year following the fiscal year specified in clause (ii), ½.

"(iv) For the fiscal year following the fiscal year specified in clause (iii), ¼.

"(F) LIMITATIONS.—

"(i) PRO-RATION FOR PARTIAL YEAR HOSPITALS.—In the case of an eligible hospital that is a meaningful HIT user for only a portion of a fiscal year for reasons such as the hospital did not provide services for which payment is made under this section for a portion of the fiscal year or the hospital changed the use of health information technology during the fiscal year, the Secretary may pro-rate the appli-

cable amount specified under subparagraph (A) to reflect the portion of the fiscal year during which the hospital was a meaningful HIT user.

"(ii) FORM OF PAYMENT.—The payment under this subsection for a fiscal year may be in the form of a single consolidated payment or in the form of such periodic installments as the Secretary may specify.

There shall be no incentive payment under this subsection, or payment adjustment under subsection (b)(3)(B)(ix), for a fiscal year in the case of an eligible hospital for which the sum of the inpatient-bed days described in subclauses (I) and (II) of subparagraph (D)(i), for a period specified by the Secretary with respect to such fiscal year, is an amount that is less than 1,000.

"(3) MEANINGFUL HIT USER.—

"(A) IN GENERAL.—For purposes of paragraph (1), an eligible hospital shall be treated as a meaningful HIT user for a fiscal year if the eligible hospital demonstrates to the satisfaction of the Secretary that the hospital is

meaningfully using a certified health information technology system with respect to such fiscal year, as demonstrated in accordance with applicable measures established under subparagraph (B).

"(B) STANDARDS FOR MEANINGFUL USE.—The Secretary shall establish measures under which an eligible hospital may demonstrate meaningful use of a certified health information technology system for a fiscal year. Such measures may include—

"(i) self-certification of operational use of such a system;

"(ii) the submission (or ability to submit), in a form and manner specified by the Secretary (which may include the manner used for purposes of subsection (b)(3)(B)(viii)), of such information on clinical measures and data (that does not include individually identifiable health information) from such system that indicates a meaningful utilization of such a system during the year; and

"(iii) such other means as the Secretary may specify.

The Secretary may establish and apply different measures based on the stage of implementation or adoption of the certified health information technology system involved or based on the characteristics (such as size) of the hospital.

"(C) AUTHORITY TO REVISE MEASURES.—The Secretary may periodically revise the measures established under subparagraph (B) with respect to demonstrating meaningful use of a certified health information technology system.

"(4) APPLICATION.—

"(A) LIMITATIONS ON REVIEW.—There shall be no administrative or judicial review under 1869, section 1878, or otherwise of—

"(i) the determination of measures applicable to services furnished by eligible hospitals under this subsection;

"(ii) the determination of a meaningful HIT user under paragraph (3)(A) and the exception under subsection (b)(3)(B)(ix)(III); and

"(iii) the determination of any incentive payment under this subsection and the payment adjustment under subsection (b)(3)(B)(ix).

"(B) POSTING ON WEBSITE.—The Secretary shall post on the Internet website of the Centers for Medicare & Medicaid Services, in an easily understandable format, a list of the names of the eligible hospitals that are meaningful HIT users and other relevant data as determined appropriate by the Secretary. The Secretary shall ensure that a hospital has the opportunity to review the other relevant data that are to be made public with respect to the hospital prior to such data being made public.

"(5) APPLICATION TO CERTAIN MA HOSPITALS.—Notwithstanding section 1851(i)(1), an eligible hospital that is under common corporate governance with a qualifying MA organization (as defined in section 1853(l)(5)) and that serves individuals enrolled under a plan offered by such organization shall be eligible for an incentive payment under this subsection in the same manner as an eligible hospital that is not under such common corporate governance with a qualifying MA organization.

"(6) DATE SPECIFIED.—The date specified in this paragraph is the date on which the open source health information technology system under section

3001(c)(4) of the Public Health Service Act is first made publicly available.

"(7) DEFINITIONS.—For purposes of this subsection and subsection (b)(3)(B)(ix):

"(A) CERTIFIED HEALTH INFORMATION TECHNOLOGY SYSTEM.—The term 'certified health information technology system' means, with respect to an eligible hospital and a fiscal year, a health information technology system (as defined in section 3000 of the Public Health Service Act) that has a current certification under section 3001(c)(3) of such Act as satisfying all interoperability standards, privacy and security standards, and clinical and quality functions adopted under section 3003(a) of such Act as of a date specified by the Secretary with respect to such fiscal year that are applicable to the eligible hospital.

"(B) ELIGIBLE HOSPITAL.—The term 'eligible hospital' means a subsection (d) hospital.".

(b) INCENTIVE MARKET BASKET ADJUSTMENT.—Section 1886(b)(3)(B) of the Social Security Act (42 U.S.C. 1395ww(b)(3)(B)) is amended—

(1) in clause (viii)(I), by inserting "(or, beginning with fiscal year 2016, by one-half)" after "2.0 percentage points"; and

(2) by adding at the end the following new clause:

"(ix)(I) Subject to the third sentence of subsection (o)(2)(F), for purposes of clause (i) for fiscal year 2016 and each subsequent fiscal year, in the case of a subsection (d) hospital that is not a meaningful HIT user (as defined in subsection (o)(3)) with respect to such fiscal year, one-half of the applicable percentage increase otherwise applicable under clause (i) for such fiscal year shall be reduced by 25 percent for fiscal year 2016, 50 percent for fiscal year 2017, 75 percent for fiscal year 2018, and 100 percent for fiscal year 2019 and each subsequent fiscal year. Such reduction shall apply only with respect to the fiscal year involved and the Secretary shall not take into account such reduction in computing the applicable percentage increase under clause (i) for a subsequent fiscal year.

"(II) The Secretary may, on a case-by-case basis, exempt a subsection (d) hospital from the application of subclause (I) with respect to a fiscal year if the Secretary determines, subject to annual renewal, that requiring such hospital to be a meaningful HIT user during such fiscal

year would result in a significant hardship, such as in the case of a hospital in a rural area without sufficient Internet access. In no case may a hospital be granted an exemption under this subclause for more than 5 years.".

(c) CONFORMING AMENDMENT.—Section 1851(i)(1) of such Act (42 U.S.C. 1395w–21(i)(1)) is amended by striking "and 1886(h)(3)(D)" and inserting "1886(h)(3)(D), and 1886(o)(6)".

(d) GAO STUDY AND REPORT.—

(1) STUDY.—The Comptroller General of the United States shall conduct a study to determine the extent to which and manner in which payment incentives (such as under title XVIII or XIX of the Social Security Act) and other funding for purposes of implementing and using health information technology should be made available to health care settings that are receiving minimal or no payments or other funding under this Act, title XVIII or XIX of the Social Security Act, or otherwise, for such purposes. Such health care settings may include skilled nursing facilities, home health agencies, hospice programs, laboratories, federally qualified health centers, and pediatric hospitals. Such study shall include an examination of—

(A) the adoption rates of certified health information technology systems at such settings;

(B) the clinical utility of such systems at such settings;

(C) whether the services furnished at such settings are appropriate for or would benefit from the use of such systems;

(D) the potential costs and the potential benefits of providing such settings with incentive payments and other funding for such purposes; and

(E) any other issues the Comptroller General deems to be appropriate.

(2) REPORT.—Not later than June 30, 2010, the Comptroller General shall submit to Congress a report on the findings and conclusions of the study conducted under paragraph (1).

SEC. 303. INCENTIVES FOR CERTAIN MEDICARE ADVANTAGE PLANS.

(a) IN GENERAL.—Section 1853 of the Social Security Act (42 U.S.C. 1395w–23) is amended—

(1) in subsection (a)(1)(A), by striking "and (i)" and inserting "(i), and (l)"; and

(2) by adding at the end the following new subsections:

"(l) APPLICATION OF ELIGIBLE PROFESSIONAL INCENTIVES FOR CERTAIN MA ORGANIZATIONS TO IMPLEMENT CERTIFIED HEALTH INFORMATION TECHNOLOGY SYSTEMS.—

"(1) IN GENERAL.—Subject to paragraphs (3) and (4), in the case of a qualifying MA organization, the provisions of sections 1848(o) and 1848(a)(7) shall apply with respect to eligible professionals described in paragraph (2) of the organization who the organization attests under section 1854(a)(1)(A)(iv) to be meaningful HIT users under in a similar manner as they apply to eligible professionals in a group practice under such sections.

"(2) ELIGIBLE PROFESSIONALS DESCRIBED.—With respect to a qualifying MA organization, eligible professionals described in this paragraph are eligible professionals (as defined for purposes of section 1848(o)) who—

"(A) are employed by the organization or are employed by or partners of an entity that, through contract with the organization, provides its services predominantly or exclusively to enrollees of such organization; and

"(B) furnish, on average, at least 20 hours per week of professional services.

"(3) INCENTIVE PAYMENTS.—In applying section 1848(o) under paragraph (1), instead of the additional payment amount under subparagraph (A) of section 1848(o)(1), there shall be substituted the maximum amount permitted under such section multiplied by the medicare share (as determined by the Secretary). Such medicare share for an organization shall be determined in a manner so as to result in the same aggregate payments to the organization as would be paid under section 1848(o) to the eligible professionals described in paragraph (2)(A) for services furnished under part B of this title.

"(4) PAYMENT ADJUSTMENT.—

"(A) IN GENERAL.—In applying section 1848(a)(7) under paragraph (1), instead of the payment adjustment being an applicable percent of the fee schedule amount for a year under such section, the payment adjustment under paragraph (1) shall be equal to the percent specified in subparagraph (B) for such year of the payment amount otherwise provided under this section for the year.

"(B) SPECIFIED PERCENT.—The percent specified under this subparagraph for—

"(i) 2016 is 99.6 percent;

"(ii) 2017 is 99.2 percent;

"(iii) 2018 is 98.8 percent; and

"(iv) 2019 and each subsequent year is 98.4 percent.

"(5) QUALIFYING MA ORGANIZATION DEFINED.—In this subsection and subsection (m), the term 'qualifying MA organization' means an organization that is organized as a health maintenance organization (as defined in section 2791(b)(3) of the Public Health Service Act) that offers one or more MA plans under which the physicians furnishing physicians' services under such a plan are predominantly either employees of the organization or are employees or partners of an entity that, through contract with the organization, provides its services predominantly or exclusively to enrollees of such organization.

"(m) ELIGIBLE HOSPITAL INCENTIVES FOR CERTAIN MA ORGANIZATIONS TO IMPLEMENT CERTIFIED HEALTH INFORMATION TECHNOLOGY SYSTEMS.—

"(1) IN GENERAL.—Subject to paragraph (3), in the case of a qualifying MA organization (as de-

fined in section 1853(l)(5)), if, according to the attestation of the organization submitted under section 1854(a)(1)(A)(iv) for a year, one or more eligible hospitals (as defined in section 1886(o)(7)(B)) that are under common corporate governance with such organization and that serve individuals enrolled under a plan offered by such organization are not meaningful HIT users (as defined in section 1886(o)(3) with respect to a year, the payment amount payable under this section for such organization for such year shall be—

"(A) reduced by a percent specified by the Secretary for such year; or

"(B) in the case the Secretary is not able to specify reductions under subparagraph (A) because of insufficient encounter data or other appropriate date, the amount that is equal to the percent specified under paragraph (2) of the payment amount otherwise provided under this section to the organization for the year.

Reductions specified by the Secretary under subparagraph (A) shall be determined in a manner so as to result in the same aggregate reductions to the organization as would be applied under section 1886(b)(3)(B)(ix) to all such eligible hospitals under

common corporate governance with such organization if payment for inpatient services furnished by such hospitals was payable under part A instead of this part.

"(2) ALTERNATIVE PERCENT SPECIFIED.—The percent specified under this paragraph for—

"(A) 2016 is 99.95 percent;

"(B) 2017 is 99.90 percent;

"(C) 2018 is 99.85 percent; and

"(D) 2019 and each subsequent year is 99.80 percent.

"(3) LIMITATION.—In no case may the application of subsection (l) and this subsection with respect to a year result in a payment amount payable under this section for a qualifying MA organization for the year that is less than the amount that is equal to the percent specified under paragraph (4) of the payment amount that would otherwise be provided under this section to the organization for the year without regard to subsection (l) and this subsection.

"(4) SPECIFIED PERCENT.—The percent specified under this paragraph for—

"(A) 2016 is 99 percent;

"(B) 2017 is 98 percent;

"(C) 2018 is 97 percent; and

"(D) 2019 and each subsequent year is 96 percent.".

(b) MEANINGFUL HIT USER ATTESTATION WITH BIDS.—Section 1854(a)(1)(A) of the Social Security Act (42 U.S.C. 1395w–24(a)(1)(A)) is amended by adding at the end the following new clause:

"(iv) An attestation identifying whether each eligible professional described in section 1853(l)(2) with respect to such organization is a meaningful HIT user (as defined in section 1848(o)(3)) for the year and whether each eligible hospital described in section 1853(m)(1), with respect to such organization, is a meaningful HIT user (as defined in section 1886(o)(3)) for the year.".

(c) HIT INCENTIVE PAYMENTS EXEMPT FROM BENCHMARK DETERMINATIONS.—Section 1853(c) of the Social Security Act (42 U.S.C. 1395w–23(c)) is amended—

(1) in paragraph (1)(D)(i), by striking "section 1886(h)" and inserting "sections 1848(o), 1886(h), and 1886(o)"; and

(2) in paragraph (6)(A), by inserting after "under part B," the following: "excluding expenditures attributable to sections 1848(o) and 1886(o)".

(d) CONFORMING AMENDMENT.—Section 1853(f) of such Act (42 U.S.C. 1395w–23(f)) is amended by inserting "and for payments under subsection (l)" after "with the organization".

Subtitle B—Other Incentives for the Implementation and Use of Health Information Technology

SEC. 311. GRANT, LOAN, AND DEMONSTRATION PROGRAMS.

Title XXX of the Public Health Service Act, as added by section 101, is amended by adding at the end the following new subtitle:

"Subtitle B—Incentives for the Use of Health Information Technology

"SEC. 3011. GRANTS AND LOANS TO FACILITATE THE WIDESPREAD ADOPTION OF QUALIFIED HEALTH INFORMATION TECHNOLOGY.

"(a) COMPETITIVE GRANTS TO FACILITATE THE WIDESPREAD ADOPTION OF HEALTH INFORMATION TECHNOLOGY.—

"(1) IN GENERAL.—The National Coordinator may award competitive grants to eligible entities to purchase qualified health information technology.

"(2) QUALIFIED HEALTH INFORMATION TECHNOLOGY.—For purposes of this section, the term 'qualified health information technology' means health information technology that consists of hardware, software, or the provision of support services and that—

"(A) enables the protection of health information, in accordance with applicable law;

"(B) is (or is necessary for the operation of) an electronic health records system, including the provision of decision support and physician order entry for medications;

"(C) has the ability to allow timely and permissible access to patient information and to transmit and exchange health information among providers, patients, or insurers; and

"(D) is certified under the program developed under section 3001(c)(3) to be in compliance with any applicable standards adopted under section 3003(a).

"(3) ELIGIBILITY.—To be eligible to receive a grant under paragraph (1) an entity shall—

"(A) submit to the National Coordinator an application at such time and in such manner

as the National Coordinator may require, and containing—

"(i) a plan on how the entity intends to maintain and support the qualified health information technology that would be purchased with amounts under such grant, including the type of resources expected to be involved; and

"(ii) such other information as the National Coordinator may require;

"(B) submit to the National Coordinator a plan for how qualified health information technology purchased by the entity will result in the electronic exchange and use of health information;

"(C) be—

"(i) a not for profit hospital or a Federally qualified health center (as defined in section 1861(aa)(4) of the Social Security Act);

"(ii) an individual or group practice; or

"(iii) another health care provider, such as a rural health clinic, not described in clause (i) or (ii);

"(D) demonstrate significant financial need;

"(E) agree to notify individuals in accordance with section 402 of the Health-e Information Technology Act of 2008 (relating to notifications in the case of breaches);

"(F) provide matching funds in accordance with paragraph (5);

"(G) consult with the Health Information Technology Resource Center established under section 3006 to access the knowledge and experience of existing initiatives regarding the successful implementation and effective use of health information technology; and

"(H) link, to the extent practicable, to one or more local or regional health information plans.

"(4) USE OF FUNDS.—Amounts received under a grant under this subsection shall be used to facilitate the purchase of qualified health information technology.

"(5) MATCHING REQUIREMENT.—To be eligible for a grant under this subsection an entity shall contribute non-Federal contributions to the costs of carrying out the activities for which the grant is award-

ed in an amount equal to $1 for each $3 of Federal funds provided under the grant.

"(6) PREFERENCE IN AWARDING GRANTS.—

"(A) IN GENERAL.—In awarding grants under this subsection the National Coordinator shall give preference to the following eligible entities:

"(i) Small health care providers.

"(ii) Entities that are located in rural and other areas that serve uninsured, underinsured, and medically underserved individuals (regardless of whether such area is urban or rural).

"(iii) Nonprofit health care providers.

"(iv) Health care providers (such as children's hospitals, pediatricians, obstetrician-gynecologists, and hospitals that serve uninsured, underinsured, and medically underserved individuals and that have limited Medicare patient loads) that have not received any funds, or have received a minimal amount of funds, under sections 1848(o) and 1886(o) of the Social Security Act.

"(B) CONSIDERATION.—In awarding grants to entities under this subsection, the National Coordinator shall take into account the amount of funds provided to such entities under other laws, including under sections 1848(o) and 1886(o) of the Social Security Act.

"(7) ADDITIONAL SOURCES OF FUNDING FOR HEALTH INFORMATION TECHNOLOGY.—Funding made available under this subsection is in addition to funding which may be used toward the acquisition and utilization of health information technology under other law, which includes the following:

"(A) Medicaid transformation grants under section 1903(z) of the Social Security Act.

"(B) Grants or funding available through the Agency for Healthcare Research and Quality.

"(C) Grants or funding that may be available through the Health Resources and Services Administration for investment in health information technologies or telehealth.

"(D) Grants or funding that may be available through the Department of Agriculture's

Rural Development Telecommunications Program for investment in telemedicine.

"(E) Sections 1848(o) and 1886(o) of the Social Security Act.

"(b) COMPETITIVE GRANTS TO STATES AND INDIAN TRIBES FOR THE DEVELOPMENT OF LOAN PROGRAMS TO FACILITATE THE WIDESPREAD ADOPTION OF QUALIFIED HEALTH INFORMATION TECHNOLOGY.—

"(1) IN GENERAL.—The National Coordinator may award competitive grants to eligible entities for the establishment of programs for loans to health care providers to purchase qualified health information technology.

"(2) ELIGIBLE ENTITY DEFINED.—For purposes of this subsection, the term 'eligible entity' means a State or Indian tribe (as defined in the Indian Self-Determination and Education Assistance Act) that—

"(A) submits to the National Coordinator an application at such time, in such manner, and containing such information as the National Coordinator may require;

"(B) submits to the National Coordinator a strategic plan in accordance with paragraph (4) and provides to the National Coordinator

assurances that the entity will update such plan annually in accordance with such paragraph;

"(C) provides assurances to the National Coordinator that the entity will establish a Loan Fund in accordance with paragraph (3);

"(D) provides assurances to the National Coordinator that the entity will not provide a loan from the Loan Fund to a health care provider unless the provider meets each of the conditions described in paragraph (5); and

"(E) agrees to provide matching funds in accordance with paragraph (9).

"(3) ESTABLISHMENT OF FUND.—For purposes of paragraph (2)(C), an eligible entity shall establish a qualified health information technology loan fund (referred to in this subsection as a 'Loan Fund') and comply with the other requirements contained in this section. A grant to an eligible entity under this subsection shall be deposited in the Loan Fund established by the eligible entity. No funds authorized by other provisions of this subtitle to be used for other purposes specified in this subtitle shall be deposited in any Loan Fund.

"(4) STRATEGIC PLAN.—

"(A) IN GENERAL.—For purposes of paragraph (2)(B), a strategic plan of an eligible entity under this paragraph shall identify the intended uses of amounts available to the Loan Fund of such entity.

"(B) CONTENTS.—A strategic plan under subparagraph (A), with respect to a Loan Fund of an eligible entity, shall include for a year the following:

"(i) A list of the projects to be assisted through the Loan Fund during such year.

"(ii) A description of the criteria and methods established for the distribution of funds from the Loan Fund during the year.

"(iii) A description of the financial status of the Loan Fund as of the date of submission of the plan.

"(iv) The short-term and long-term goals of the Loan Fund.

"(5) HEALTH CARE PROVIDER CONDITIONS FOR RECEIPT OF LOANS.—For purposes of paragraph (2)(D), the conditions described in this paragraph, with respect to a health care provider that seeks a

loan from a Loan Fund established under this subsection, are the following:

"(A) The health care provider links, to the extent practicable, to one or more local or regional health information networks.

"(B) The health care provider consults with the Health Information Technology Resource Center established under section 3006 to access the knowledge and experience of existing initiatives regarding the successful implementation and effective use of health information technology.

"(C) The health care provider agrees to notify individuals in accordance with section 402 of the Health-e Information Technology Act of 2008 (relating to notifications in the case of breaches).

"(D) The health care provider submits to the State or Indian tribe involved a plan on how the health care provider intends to maintain and support the qualified health information technology that would be purchased with such loan, including the type of resources expected to be involved and any such other information as

the State or Indian Tribe, respectively, may require.

"(6) USE OF FUNDS.—

"(A) IN GENERAL.—Amounts deposited in a Loan Fund, including loan repayments and interest earned on such amounts, shall be used only for awarding loans or loan guarantees, making reimbursements described in paragraph (8)(D)(I), or as a source of reserve and security for leveraged loans, the proceeds of which are deposited in the Loan Fund established under paragraph (1). Loans under this section may be used by a health care provider to purchase qualified health information technology.

"(B) LIMITATION.—Amounts received by an eligible entity under this subsection may not be used—

"(i) for the purchase or other acquisition of any health information technology system that is not a qualified health information technology; or

"(ii) to conduct activities for which Federal funds are expended under this title.

"(7) TYPES OF ASSISTANCE.—Except as otherwise limited by applicable State law, amounts deposited into a Loan Fund under this subsection may only be used for the following:

"(A) To award loans that comply with the following:

"(i) The interest rate for each loan shall not exceed the market interest rate.

"(ii) The principal and interest payments on each loan shall commence not later than 1 year after the date the loan was awarded, and each loan shall be fully amortized not later than 10 years after the date of the loan.

"(iii) The Loan Fund shall be credited with all payments of principal and interest on each loan awarded from the Loan Fund.

"(B) To guarantee, or purchase insurance for, a local obligation (all of the proceeds of which finance a project eligible for assistance under this subsection) if the guarantee or purchase would improve credit market access or reduce the interest rate applicable to the obligation involved.

"(C) As a source of revenue or security for the payment of principal and interest on revenue or general obligation bonds issued by the eligible entity if the proceeds of the sale of the bonds will be deposited into the Loan Fund.

"(D) To earn interest on the amounts deposited into the Loan Fund.

"(E) To make reimbursements described in paragraph (8)(D)(I).

"(8) ADMINISTRATION OF LOAN FUNDS.—

"(A) COMBINED FINANCIAL ADMINISTRATION.—An eligible entity may (as a convenience and to avoid unnecessary administrative costs) combine, in accordance with applicable State law, the financial administration of a Loan Fund established under this subsection with the financial administration of any other revolving fund established by the entity if otherwise not prohibited by the law under which the Loan Fund was established.

"(B) COST OF ADMINISTERING FUND.—Each eligible entity may annually use not to exceed 4 percent of the funds provided to the entity under a grant under this subsection to pay the reasonable costs of the administration of

the programs under this section, including the recovery of reasonable costs expended to establish a Loan Fund which are incurred after the date of the enactment of this title.

"(C) GUIDANCE AND REGULATIONS.—The National Coordinator shall publish guidance and promulgate regulations as may be necessary to carry out the provisions of this subsection, including—

"(i) provisions to ensure that each eligible entity commits and expends funds allotted to the entity under this subsection as efficiently as possible in accordance with this title and applicable State laws; and

"(ii) guidance to prevent waste, fraud, and abuse.

"(D) PRIVATE SECTOR CONTRIBUTIONS.—

"(i) IN GENERAL.—A Loan Fund established under this subsection may accept contributions from private sector entities, except that such entities may not specify the recipient or recipients of any loan issued under this subsection. An eligible entity may agree to reimburse a private sector entity for any contribution made

under this subparagraph, except that the amount of such reimbursement may not be greater than the principal amount of the contribution made.

"(ii) AVAILABILITY OF INFORMATION.—An eligible entity shall make publicly available the identity of, and amount contributed by, any private sector entity under clause (i) and may issue letters of commendation or make other awards (that have no financial value) to any such entity.

"(9) MATCHING REQUIREMENTS.—

"(A) IN GENERAL.—The National Coordinator may not make a grant under paragraph (1) to an eligible entity unless the entity agrees to make available (directly or through donations from public or private entities) non-Federal contributions in cash to the costs of carrying out the activities for which the grant is awarded in an amount equal to not less than $1 for each $1 of Federal funds provided under the grant.

"(B) DETERMINATION OF AMOUNT OF NON-FEDERAL CONTRIBUTION.—In determining the amount of non-Federal contributions that an eligible entity has provided pursuant to sub-

paragraph (A), the National Coordinator may not include any amounts provided to the entity by the Federal Government.

"(10) REPORTS.—The National Coordinator shall annually submit to the Committee on Health, Education, Labor, and Pensions and the Committee on Finance of the Senate, and the Committees on Energy and Commerce and Ways and Means of the House of Representatives, a report summarizing the reports received by the National Coordinator from each eligible entity that receives a grant under this subsection.

"(c) COMPETITIVE GRANTS FOR THE IMPLEMENTATION OF REGIONAL OR LOCAL HEALTH INFORMATION TECHNOLOGY PLANS.—

"(1) IN GENERAL.—The National Coordinator may award competitive grants to eligible entities to implement regional or local health information plans to improve health care quality and efficiency through the electronic exchange and use of health information.

"(2) ELIGIBILITY.—To be eligible to receive a grant under paragraph (1) an entity shall—

"(A) facilitate the electronic exchange and use of health information within the local or regional area and among local and regional areas;

"(B) demonstrate financial need to the National Coordinator;

"(C) demonstrate that one of its principal missions or purposes is to use information technology to improve health care quality and efficiency;

"(D) adopt bylaws, memoranda of understanding, or other charter documents that demonstrate that the governance structure and decisionmaking processes of such entity allow for participation on an ongoing basis by multiple stakeholders within a community, including—

"(i) physicians (as defined in section 1861(r)) of the Social Security Act), including physicians that provide services to low income populations and populations that are uninsured, underinsured, and medically underserved (including such populations in urban and rural areas);

"(ii) other health care providers, such as hospitals that serve uninsured, under-

insured, and medically underserved individuals;

"(iii) patient or consumer organizations that reflect the population to be served;

"(iv) employers;

"(v) public health agencies; and

"(vi) such other entities, as determined appropriate by the National Coordinator;

"(E) demonstrate the participation, to the extent practicable, of stakeholders in the electronic exchange and use of health information within the local or regional health information plan pursuant to subparagraph (D);

"(F) adopt nondiscrimination and conflict of interest policies that demonstrate a commitment to open, fair, and nondiscriminatory participation in the regional or local health information plan by all stakeholders;

"(G) comply with applicable standards adopted under section 3003(a);

"(H) prepare and submit to the National Coordinator an application in accordance with paragraph (3); and

"(I) agree to provide matching funds in accordance with paragraph (6).

"(3) APPLICATION.—

"(A) IN GENERAL.—To be eligible to receive a grant under paragraph (1), an entity shall submit to the National Coordinator an application at such time, in such manner, and containing such information (in addition to information required under subparagraph (B)), as the National Coordinator may require.

"(B) REQUIRED INFORMATION.—At a minimum, an application submitted under this paragraph shall include—

"(i) clearly identified short-term and long-term objectives of the regional or local health information plan;

"(ii) an estimate of costs of the hardware, software, training, and other services necessary to implement the regional or local health information plan;

"(iii) a strategy that includes initiatives to improve health care quality and efficiency;

"(iv) a plan that describes provisions to encourage the electronic exchange and

use of health information by all physicians, including single physician practices and small physician groups, participating in the health information plan;

"(v) a plan to ensure the privacy and security of individually identifiable health information that is consistent with applicable Federal and State law;

"(vi) a governance plan that defines the manner in which the stakeholders shall jointly make policy and operational decisions on an ongoing basis;

"(vii) a financial or business plan that describes—

"(I) the sustainability of the plan;

"(II) the financial costs and benefits of the plan; and

"(III) the entities to which such costs and benefits will accrue;

"(viii) a plan on how the entity involved intends to maintain and support the regional or local health information plan, including the type of resources expected to be involved; and

"(ix) in the case of an applicant that is unable to demonstrate the participation of all stakeholders pursuant to paragraph (2)(D), the justification from the entity for any such nonparticipation.

"(4) USE OF FUNDS.—Amounts received under a grant under paragraph (1) shall be used to establish and implement a regional or local health information plan in accordance with this subsection.

"(5) PREFERENCE.—In awarding grants under paragraph (1), the Secretary shall give preference to eligible entities that intend to use amounts received under a grant to establish or implement a regional or local health information plan that encompasses communities with health disparities or areas that serve uninsured, underinsured, and medically underserved individuals (including urban and rural areas).

"(6) MATCHING REQUIREMENT.—

"(A) IN GENERAL.—The National Coordinator may not make a grant under this subsection to an entity unless the entity agrees that, with respect to the costs of carrying out the activities for which the grant is awarded, the entity will make available (directly or through donations from public or private enti-

ties) non-Federal contributions toward such costs in an amount equal to not less than 50 percent of such costs ($1 for each $2 of Federal funds provided under the grant).

"(B) DETERMINATION OF AMOUNT CONTRIBUTED.—Non-Federal contributions required under subparagraph (A) may be in cash or in kind, fairly evaluated, including equipment, technology, or services. Amounts provided by the Federal Government, or services assisted or subsidized to any significant extent by the Federal Government, may not be included in determining the amount of such non-Federal contributions.

"(d) REPORTS.—Not later than 1 year after the date on which the first grant is awarded under this section, and annually thereafter during the grant period, an entity that receives a grant under this section shall submit to the National Coordinator a report on the activities carried out under the grant involved. Each such report shall include—

"(1) a description of the financial costs and benefits of the project involved and of the entities to which such costs and benefits accrue;

"(2) an analysis of the impact of the project on health care quality and safety;

"(3) a description of any reduction in duplicative or unnecessary care as a result of the project involved;

"(4) a description of the efforts of recipients under this section to facilitate secure patient access to health information;

"(5) an analysis of the effectiveness of the project involved on ensuring the privacy and security of individually identifiable health information in accordance with applicable Federal and State law; and

"(6) other information as required by the National Coordinator.

"(e) REQUIREMENT TO IMPROVE QUALITY OF CARE AND DECREASE IN COSTS.—The National Coordinator shall annually evaluate the activities conducted under this section and shall, in awarding grants, implement the lessons learned from such evaluation in a manner so that awards made subsequent to each such evaluation are made in a manner that, in the determination of the National Coordinator, will result in the greatest improvement in quality of care and decrease in costs.

"(f) LIMITATION.—An eligible entity may only receive one non-renewable grant under subsection (a), one non-

renewable grant under subsection (b), and one non-renewable grant under subsection (c).

"(g) SMALL HEALTH CARE PROVIDER.—For purposes of this section, the term 'small health care provider' means a health care provider that has an average of 10 or fewer full-time equivalent employees during the period involved.

"(h) AUTHORIZATION OF APPROPRIATIONS.—

"(1) IN GENERAL.—For the purpose of carrying out subsections (a) through (d), there is authorized to be appropriated $115,000,000 for each of the fiscal years 2009 through 2013.

"(2) AVAILABILITY.—Amounts appropriated under paragraph (1) shall remain available through fiscal year 2013.

"SEC. 3012. DEMONSTRATION PROGRAM TO INTEGRATE INFORMATION TECHNOLOGY INTO CLINICAL EDUCATION.

"(a) IN GENERAL.—The Secretary may award grants under this section to carry out demonstration projects to develop academic curricula integrating qualified health information technology in the clinical education of health professionals. Such awards shall be made on a competitive basis and pursuant to peer review.

"(b) ELIGIBILITY.—To be eligible to receive a grant under subsection (a), an entity shall—

"(1) submit to the Secretary an application at such time, in such manner, and containing such information as the Secretary may require;

"(2) submit to the Secretary a strategic plan for integrating qualified health information technology in the clinical education of health professionals to reduce medical errors and enhance health care quality;

"(3) be—

"(A) a school of medicine, osteopathic medicine, dentistry, or pharmacy, a graduate program in behavioral or mental health, or any other graduate health professions school;

"(B) a graduate school of nursing or physician assistant studies;

"(C) a consortium of two or more schools described in subparagraph (A) or (B); or

"(D) an institution with a graduate medical education program in medicine, osteopathic medicine, dentistry, pharmacy, nursing, or physician assistance studies;

"(4) provide for the collection of data regarding the effectiveness of the demonstration project to be

funded under the grant in improving the safety of patients, the efficiency of health care delivery, and in increasing the likelihood that graduates of the grantee will adopt and incorporate qualified health information technology, in the delivery of health care services; and

"(5) provide matching funds in accordance with subsection (d).

"(c) USE OF FUNDS.—

"(1) IN GENERAL.—With respect to a grant under subsection (a), an eligible entity shall—

"(A) use grant funds in collaboration with 2 or more disciplines; and

"(B) use grant funds to integrate qualified health information technology into community-based clinical education.

"(2) LIMITATION.—An eligible entity shall not use amounts received under a grant under subsection (a) to purchase hardware, software, or services.

"(d) MATCHING FUNDS.—

"(1) IN GENERAL.—The Secretary may award a grant to an entity under this section only if the entity agrees to make available non-Federal contributions toward the costs of the program to be

funded under the grant in an amount that is not less than $1 for each $2 of Federal funds provided under the grant.

"(2) DETERMINATION OF AMOUNT CONTRIBUTED.—Non-Federal contributions under paragraph (1) may be in cash or in kind, fairly evaluated, including equipment or services. Amounts provided by the Federal Government, or services assisted or subsidized to any significant extent by the Federal Government, may not be included in determining the amount of such contributions.

"(e) EVALUATION.—The Secretary shall take such action as may be necessary to evaluate the projects funded under this section and publish, make available, and disseminate the results of such evaluations on as wide a basis as is practicable.

"(f) REPORTS.—Not later than 1 year after the date of enactment of this title, and annually thereafter, the Secretary shall submit to the Committee on Health, Education, Labor, and Pensions and the Committee on Finance of the Senate, and the Committees on Energy and Commerce and Ways and Means of the House of Representatives a report that—

"(1) describes the specific projects established under this section; and

"(2) contains recommendations for Congress based on the evaluation conducted under subsection (e).

"(g) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated to carry out this section, $10,000,000 for each of fiscal years 2009 through 2011.

"(h) SUNSET.—This section shall not apply after September 30, 2011.".

TITLE IV—PRIVACY AND SECURITY PROVISIONS

SEC. 400. DEFINITIONS.

In this title, except as specified otherwise:

(1) BREACH.—The term "breach" means the unauthorized acquisition, access, or disclosure of protected health information which compromises the security, privacy, or integrity of protected health information maintained by or on behalf of a person. Such term does not include any unintentional acquisition or access of such information by an employee or agent of the covered entity or business associate involved if such acquisition or access, respectively, was made in good faith and within the course and scope of the employment or other contractual relationship of such employee or agent, respectively, with the covered entity or business associate and if

such information is not further acquired, accessed, or disclosed by such employee or agent.

(2) BUSINESS ASSOCIATE.—The term "business associate" has the meaning given such term in section 160.103 of title 45, Code of Federal Regulations.

(3) COVERED ENTITY.—The term "covered entity" has the meaning given such term in section 160.103 of title 45, Code of Federal Regulations.

(4) DISCLOSE.—The terms "disclose" and "disclosure" have the meaning given the term "disclosure" in section 160.103 of title 45, Code of Federal Regulations.

(5) ELECTRONIC HEALTH RECORD.—The term "electronic health record" means an electronic record of health-related information on an individual that is created, gathered, managed, and consulted by authorized health care clinicians and staff of one or more organizations, that conforms to standards adopted under section 3003(a) of the Public Health Service Act, as added by section 101, and is made accessible electronically to other health care organizations and other authorized users.

(6) ELECTRONIC MEDICAL RECORD.—The term "electronic medical record" means an electronic

record of individually identifiable health information on an individual that is created, gathered, managed, and consulted by authorized health care clinicians and staff within a single organization.

(7) HEALTH CARE OPERATIONS.—The term "health care operation" has the meaning given such term in section 164.501 of title 45, Code of Federal Regulations.

(8) HEALTH CARE PROVIDER.—The term "health care provider" has the meaning given such term in section 160.103 of title 45, Code of Federal Regulations.

(9) HEALTH PLAN.—The term "health plan" has the meaning given such term in section 1171(5) of the Social Security Act, as amended by section 415.

(10) NATIONAL COORDINATOR.—The term "National Coordinator" means the head of the Office of the National Coordinator for Health Information Technology established under section 3001(a) of the Public Health Service Act, as added by section 101.

(11) PAYMENT.—The term "payment" has the meaning given such term in section 164.501 of title 45, Code of Federal Regulations.

(12) PERSONAL HEALTH RECORD.—The term "personal health record" means an electronic record of individually identifiable health information on an individual that can be drawn from multiple sources and that is managed, shared, and controlled by or for the individual.

(13) PROTECTED HEALTH INFORMATION.—The term "protected health information" has the meaning given such term in section 160.103 of title 45, Code of Federal Regulations.

(14) SECRETARY.—The term "Secretary" means the Secretary of Health and Human Services.

(15) SECURITY.—The term "security" has the meaning given such term in section 164.304 of title 45, Code of Federal Regulations.

(16) STATE.—The term "State" means each of the several States, the District of Columbia, Puerto Rico, the Virgin Islands, Guam, American Samoa, and the Northern Mariana Islands.

(17) TREATMENT.—The term "treatment" has the meaning given such term in section 164.501 of title 45, Code of Federal Regulations.

(18) USE.—The term "use" has the meaning given such term in section 160.103 of title 45, Code of Federal Regulations.

(19) VENDOR OF PERSONAL HEALTH RECORDS.—The term "vendor of personal health records" means an entity that offers or maintains a personal health record. Such term does not include an entity that is a covered entity for purposes of offering or maintaining such personal health record.

Subtitle A—Improved Privacy Provisions and Security Provisions

SEC. 401. APPLICATION OF SECURITY PROVISIONS AND PENALTIES TO BUSINESS ASSOCIATES OF COVERED ENTITIES; ANNUAL GUIDANCE ON PRIVACY AND SECURITY PROVISIONS.

(a) APPLICATION OF SECURITY PROVISIONS.—Sections 164.308, 164.310, 164.312, and 164.316 of title 45, Code of Federal Regulations, and any applicable security standards adopted by the Secretary under section 3003(a) of the Public Health Service Act, as added by section 101, shall apply to a business associate of a covered entity in the same manner that such sections and standards, respectively, apply to the covered entity.

(b) APPLICATION OF CIVIL AND CRIMINAL PENALTIES.—Sections 1176 and 1177 of the Social Security Act (42 U.S.C. 1320d–5, 1320d–6) shall apply to a business associate of a covered entity with respect to a section applied under subsection (a) to such business associate in

the same manner that such sections apply to a covered entity with respect to such section.

(c) ANNUAL GUIDANCE.—Not later than 12 months after the date of the enactment of this Act and annually thereafter, the Secretary of Health and Human Services shall, in consultation with industry stakeholders, annually issue guidance on the latest privacy and security safeguard technologies for use in carrying out the sections described in subsection (a).

SEC. 402. NOTIFICATION IN THE CASE OF BREACH.

(a) IN GENERAL.—A covered entity that accesses, maintains, retains, modifies, records, stores, destroys, or otherwise holds, uses, or discloses unsecured protected health information (as defined in subsection (h)(1)) shall, in the case of a breach of such information that is discovered by the covered entity, notify each individual whose unsecured protected health information has been, or is reasonably believed by the covered entity to have been, accessed, acquired, or disclosed as a result of such breach.

(b) NOTIFICATION OF COVERED ENTITY BY BUSINESS ASSOCIATE.—A business associate of a covered entity that accesses, maintains, retains, modifies, records, stores, destroys, or otherwise holds, uses, or discloses unsecured protected health information shall, following the discovery of a breach of such information, notify the cov-

ered entity of such breach. Such notice shall include the identification of each individual whose unsecured protected health information has been, or is reasonably believed by the business associate to have been, accessed, acquired, or disclosed during such breach.

(c) BREACHES TREATED AS DISCOVERED.—For purposes of this section, a breach shall be treated as discovered by a covered entity or by a business associate as of the first day on which such breach is known to such entity or associate, respectively, (including any person that is an employee, officer, or other agent of such entity or associate, respectively) or should reasonably have been known to such entity or associate (or person) to have occurred.

(d) TIMELINESS OF NOTIFICATION.—

(1) IN GENERAL.—Subject to subsection (g), all notifications required under this section shall be made without unreasonable delay and in no case later than 60 calendar days after the discovery of a breach by the covered entity involved (or business associate involved in the case of a notification required under subsection (b)).

(2) BURDEN OF PROOF.—The covered entity involved (or business associate involved in the case of a notification required under subsection (b)), shall have the burden of demonstrating that all notifica-

tions were made as required under this subtitle, including evidence demonstrating the necessity of any delay.

(e) METHODS OF NOTICE.—

(1) INDIVIDUAL NOTICE.—Notice required under this section to be provided to an individual, with respect to a breach, shall be provided promptly and in the following form:

(A) Written notification by first-class mail to the individual (or the next of kin of the individual if the individual is deceased) at the last known address of the individual or the next of kin, respectively, or, if specified as a preference by the individual, by electronic mail. The notification may be provided in one or more mailings as information is available.

(B) In the case in which there is insufficient, or out-of-date contact information that precludes direct written (or, if specified by the individual under subparagraph (A), electronic) notification to the individual, a substitute form of notice shall be provided, including a conspicuous posting on the home page of the Web site of the covered entity involved or notice in major print or broadcast media, including

major media in geographic areas where the individuals affected by the breach likely reside. Such a notice in media will include a toll-free phone number where an individual can learn whether or not the individual's unsecured protected health information is possibly included in the breach.

(C) In any case deemed by the covered entity involved to require urgency because of possible imminent misuse of unsecured protected health information, the covered entity, in addition to notice provided under subparagraph (A), may provide information to individuals by telephone or other means, as appropriate.

(2) MEDIA NOTICE.—Notice shall be provided to prominent media outlets serving a State or jurisdiction, following the discovery of a breach described in subsection (a), if the unsecured protected health information of more than 500 residents of such State or jurisdiction is, or is reasonably believed to have been, accessed, acquired, or disclosed during such breach.

(3) NOTICE TO SECRETARY.—Notice shall be provided to the Secretary by covered entities of un-

secured protected health information that has been acquired or disclosed in a breach.

(4) POSTING ON HHS PUBLIC WEBSITE.—The Secretary shall make available to the public on the Internet website of the Department of Health and Human Services a list that identifies each covered entity involved in a breach described in subsection (a) in which the unsecured protected health information of more than 1,000 individuals is acquired or disclosed.

(f) CONTENT OF NOTIFICATION.—Regardless of the method by which notice is provided to individuals under this section, notice of a breach shall include, to the extent possible, the following:

(1) A brief description of what happened, including the date of the breach and the date of the discovery of the breach, if known.

(2) A description of the types of unsecured protected health information that were involved in the breach (such as full name, Social Security number, date of birth, home address, account number, or disability code).

(3) The steps individuals should take to protect themselves from potential harm resulting from the breach.

(4) A brief description of what the covered entity involved is doing to investigate the breach, to mitigate losses, and to protect against any further breaches.

(5) Contact procedures for individuals to ask questions or learn additional information, which shall include a toll-free telephone number, an e-mail address, Web site, or postal address.

(g) DELAY OF NOTIFICATION AUTHORIZED FOR LAW ENFORCEMENT PURPOSES.—If a law enforcement official determines that a notification, notice, or posting required under this section would impede a criminal investigation or cause damage to national security, such notification, notice, or posting shall be delayed in the same manner as provided under section 164.528(a)(2) of title 45, Code of Federal Regulations, in the case of a disclosure covered under such section.

(h) UNSECURED PROTECTED HEALTH INFORMATION.—

(1) DEFINITION.—

(A) IN GENERAL.—Subject to subparagraph (B), for purposes of this section, the term "unsecured protected health information" means protected health information that is not protected through the use of a technology or

methodology specified by the Secretary in the guidance issued under paragraph (2).

(B) EXCEPTION IN CASE TIMELY GUIDANCE NOT ISSUED.—In the case that the Secretary does not issue guidance under paragraph (2) by the date specified in such paragraph, for purposes of this section, the term "unsecured protected health information" shall mean information that is not protected by technology standards developed or endorsed by a standards developing organization that is accredited by the American National Standards Institute.

(2) GUIDANCE.—For purposes of paragraph (1) and section 415(f), not later than the date that is 60 days after the date of the enactment of this Act, the Secretary shall, after consultation with stakeholders, issue (and annually update) guidance specifying the technologies and methodologies that render protected health information unusable, unreadable, or indecipherable to unauthorized individuals.

(i) REPORT TO CONGRESS ON BREACHES.—

(1) IN GENERAL.—Not later than 12 months after the date of the enactment of this Act and annually thereafter, the Secretary shall prepare and submit to the Committee on Finance and the Com-

mittee on Health, Education, Labor, and Pensions of the Senate and the Committee on Ways and Means and the Committee on Energy and Commerce of the House of Representatives a report containing the information described in paragraph (2) regarding breaches for which notice was provided to the Secretary under subsection (e)(3).

(2) INFORMATION.—The information described in this paragraph regarding breaches specified in paragraph (1) shall include—

(A) the number and nature of such breaches;

(B) actions taken in response to such breaches; and

(C) any recommendations described in section 422(b)(9) made by the National Coordinator for the year involved.

(j) EFFECTIVE DATE.—The provisions of this section shall apply to breaches that are discovered on or after the date that is 90 days after the date of the enactment of this Act.

SEC. 403. EDUCATION ON HEALTH INFORMATION PRIVACY AND REPORT ON COMPLIANCE.

(a) REGIONAL OFFICE PRIVACY ADVISORS.—Not later than 6 months after the date of the enactment of

this Act, the Secretary shall designate an individual in each regional office of the Department of Health and Human Services to offer guidance and education to covered entities, business associates, and individuals on their rights and responsibilities related to Federal privacy and security requirements for protected health information.

(b) REPORT ON COMPLIANCE.—

(1) IN GENERAL.—Not later than 24 months after the date of the enactment of this Act and annually thereafter, the Secretary shall prepare and submit to the Committee on Finance and the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Ways and Means and the Committee on Energy and Commerce of the House of Representatives a report concerning the number of audits performed and a summary of audit findings pursuant to section 414 and complaints of alleged violations of the provisions of sections 401 and 402, the provisions of subtitle B, and the provisions of subparts C and E of title 45, Code of Federal Regulations that are received by the Secretary during the year for which the report is being prepared. Each such report shall include, with respect to such complaints received during the year—

(A) the number of such complaints;

(B) the number of such complaints resolved informally, a summary of the types of such complaints so resolved, and the number of covered entities that received technical assistance from the Secretary during such year in order to achieve compliance with such provisions and the types of such technical assistance provided;

(C) the number of such complaints that resulted in the imposition of civil money penalties, the amount of the civil money penalty imposed in each such case, and a summary of the basis for each such civil money penalty;

(D) the number of compliance reviews conducted and the outcome of each such review;

(E) the number of subpoenas or inquiries issued; and

(F) the Secretary's plan for improving compliance with and enforcement of such provisions for the following year.

(2) AVAILABILITY TO PUBLIC.—Each report under paragraph (1) shall be made available to the public on the Internet website of the Department of Health and Human Services.

(c) EDUCATION INITIATIVE ON USES OF HEALTH INFORMATION.—

(1) IN GENERAL.—Not later than 12 months after the date of the enactment of this Act, the Office for Civil Rights within the Department of Health and Human Services shall develop and maintain a multi-faceted national education initiative to enhance public transparency regarding the uses of protected health information, including programs to educate individuals about the potential uses of their protected health information, the effects of such uses, and the rights of individuals with respect to such uses. Such programs shall be conducted in a variety of languages and present information in a clear and understandable manner.

(2) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated to carry out paragraph (1), $10,000,000 for the period of fiscal years 2009 through 2013.

SEC. 404. APPLICATION OF PENALTIES TO BUSINESS ASSOCIATES OF COVERED ENTITIES FOR VIOLATIONS OF PRIVACY CONTRACT REQUIREMENTS.

(a) APPLICATION OF CONTRACT REQUIREMENTS.—In the case of a business associate of a covered entity that

obtains or creates protected health information pursuant to a written contract (or other written arrangement) described in section 164.502(e)(2) of title 45, Code of Federal Regulations, with such covered entity, the business associate may use and disclose such protected health information only if such use or disclosure, respectively, is in compliance with each applicable requirement of section 164.504(e) of such title and section 405(b).

(b) APPLICATION OF KNOWLEDGE ELEMENTS ASSOCIATED WITH CONTRACTS.—Section 164.504(e)(1)(ii) of title 45, Code of Federal Regulations, shall apply to a business associate described in subsection (a), with respect to compliance with such subsection, in the same manner that such section applies to a covered entity, with respect to compliance with the standards in sections 164.502(e) and 164.504(e) of such title, except that in applying such section 164.504(e)(1)(ii) each reference to the business associate, with respect to a contract, shall be treated as a reference to the covered entity involved in such contract.

(c) APPLICATION OF CIVIL AND CRIMINAL PENALTIES.—In the case of a business associate that violates any provision of subsection (a) or (b), the provisions of sections 1176 and 1177 of the Social Security Act (42 U.S.C. 1320d–5, 1320d–6) shall apply to the business associate with respect to such violation in the same manner

as such provisions apply to a person who violates a provision of part C of title XI of such Act.

SEC. 405. RESTRICTIONS ON CERTAIN USES AND DISCLOSURES AND SALES OF HEALTH INFORMATION; ACCOUNTING OF CERTAIN PROTECTED HEALTH INFORMATION DISCLOSURES; ACCESS TO CERTAIN INFORMATION IN ELECTRONIC FORMAT.

(a) REQUESTED RESTRICTIONS ON CERTAIN DISCLOSURES OF HEALTH INFORMATION.—In the case that an individual requests under paragraph (a)(1)(i)(A) of section 164.522 of title 45, Code of Federal Regulations, that a covered entity restrict the disclosure of the protected health information of the individual, notwithstanding paragraph (a)(1)(ii) of such section, the covered entity must comply with the requested restriction if—

(1) except as otherwise required by law, the disclosure is to a health plan for purposes of carrying out payment or health care operations (and is not for purposes of carrying out treatment); and

(2) the protected health information pertains solely to a health care item or service for which the health care provider involved has been paid out of pocket in full.

(b) DISCLOSURES REQUIRED TO BE LIMITED TO THE LIMITED DATA SET OR THE MINIMUM NECESSARY.—

(1) TRANSITIONAL RULE.—

(A) IN GENERAL.—Subject to subparagraph (B), a covered entity shall be treated as being in compliance with section 164.502(b)(1) of title 45, Code of Federal Regulations, and for purposes of section 404(a) a business associate shall be treated as being in compliance with this subsection, with respect to the use, disclosure, or request of protected health information described in such section, only if the covered entity or business associate, respectively, limits such protected health information, to the extent practicable, to either the limited data set (as defined in section 164.514(e)(2) of such title) or to the minimum necessary to accomplish the intended purpose of such use, disclosure, or request, respectively.

(B) SUNSET.—Subparagraph (A) shall not apply on and after the earlier of—

(i) the effective date on which the Secretary adopts, taking into consideration the regulations promulgated under section

406(d), the study under section 410, and the report under section 411, a standard under section 3003(a) of the Public Health Service Act, as added by section 101, which defines the term "minimum necessary" for purposes of subpart E of part 164 of title 45, Code of Federal Regulations; or

(ii) the National Coordinator recommends guidance under section 3001(c)(2) of such Act which defines such term for such purposes.

(2) DETERMINATION OF MINIMUM NECESSARY.—For purposes of paragraph (1), in the case of the disclosure of protected health information, the covered entity or business associate disclosing such information shall determine what constitute the minimum necessary to accomplish the intended purpose of such disclosure.

(3) APPLICATION OF EXCEPTIONS.—The exceptions described in section 164.502(b)(2) of title 45, Code of Federal Regulations, shall apply to the requirement under paragraph (1) as of the effective date described in section 433 in the same manner

that such exceptions apply to section 164.502(b)(1) of such title before such date.

(4) RULE OF CONSTRUCTION.—Nothing in this subsection shall be construed as affecting the use, disclosure, or request of protected health information that has been de-identified to the greatest extent practicable rather than the use of protected health information that has been limited to the limited data set.

(c) ACCOUNTING OF CERTAIN PROTECTED HEALTH INFORMATION DISCLOSURES REQUIRED IF COVERED ENTITY USES ELECTRONIC MEDICAL RECORD OR ELECTRONIC HEALTH RECORD.—

(1) IN GENERAL.—In applying section 164.528 of title 45, Code of Federal Regulations, in the case of protected health information used or maintained by a covered entity in an electronic medical record or an electronic health record—

(A) the exception under section paragraph (a)(1)(i) of such section shall not apply to disclosures (other than oral disclosures) made by such entity of such information; and

(B) an individual shall have a right to receive an accounting of disclosures described in such paragraph of such information made by

such covered entity during only the three years prior to the date on which the accounting is requested.

(2) EFFECTIVE DATE.—The provisions of this subsection shall apply to disclosures, with respect to protected health information, made by a covered entity on or after the sooner of the following dates:

(A) In the case of an entity that does not use or maintain an electronic medical record or electronic health record before the date of the enactment of this Act with respect to such information, the date on which the covered entity first uses or maintains an electronic medical record or electronic health record, with respect to such information, and in the case of an entity that uses or maintains an electronic medical record or electronic health record with respect to such information before such date of enactment, the date on which the covered entity upgrades such electronic medical record or electronic health record.

(B) If a standard that relates to technologies that allow for an accounting for disclosures made by a covered entity for purposes of treatment, payment, and health care operations

is adopted under section 3003(a) of the Public Health Service Act, as added by section 101, the date that is 6 months after the date of such adoption.

(d) PROHIBITION ON CERTAIN DISCLOSURES.—

(1) IN GENERAL.—The following uses and disclosures shall not be considered to be permitted uses or disclosures of protected health information for purposes of subparts C and E of part 164 of title 45, Code of Federal Regulations:

(A) SALE OF PROTECTED HEALTH INFORMATION.—The sale of any protected health information of an individual by a covered entity or business associate unless the covered entity or business associate obtains from the individual, in accordance with section 164.508 of title 45, Code of Federal Regulations, a valid authorization (as described in paragraph (b) of such section) to sell such information or unless the sale is for purposes of research and public health activities (as described in sections 164.501, 164.512(i), and 164.512(b) of title 45, Code of Federal Regulations) and the price charged reflects the costs of preparation and transmittal of the data for such purposes.

(B) RE-IDENTIFICATION OF DE-IDENTIFIED INFORMATION.—In the case of an entity that has received information that has been de-identified in accordance with section 164.514 of title 45, Code of Federal Regulations, the re-identification by the entity of such information.

(C) IDENTIFICATION OF INDIVIDUAL THROUGH USE OF LIMITED DATA SET.—In the case of an entity that has received a limited data set (as defined in section 164.514(e)(2) of title 45, Code of Federal Regulations), the use, alone or in combination with other information, of such set to identify the subject of the data set.

(2) LIMITATION ON CONDITION.—In no case may a covered entity condition the provision of treatment to an individual, or payment for such treatment, on the individual providing authorization described in paragraph (1)(A).

(3) CONSTRUCTION.—Nothing in this subsection shall be construed as limiting the authority of the Secretary to adopt standards and guidance under section 3003(a) of the Public Health Service Act, as added by section 101.

(4) EFFECTIVE DATE.—The provisions of this subsection shall apply to uses and disclosures made on or after the date of the enactment of this Act.

(e) ACCESS TO CERTAIN INFORMATION IN ELECTRONIC FORMAT.—In applying section 164.524 of title 45, Code of Federal Regulations, in the case that a covered entity uses or maintains an electronic medical record or electronic health record with respect to protected health information of an individual—

(1) the individual shall have a right to obtain from such covered entity a copy of such information in an electronic format; and

(2) notwithstanding paragraph (c)(4) of such section, the covered entity may not impose any fee for providing such individual with a copy of such information (or a summary or explanation of such information) if such copy (or summary or explanation) is in an electronic form.

(f) APPLICATION OF PRIVACY REGULATIONS FOR MAKING AMENDMENTS TO PROTECTED HEALTH INFORMATION TO INFORMATION IN ELECTRONIC FORMAT.—In applying section 164.526 of title 45, Code of Regulations, in the case of protected health information used or maintained by a covered entity in an electronic medical record or electronic health record, instead of any timeframes or

deadlines described in such section the Secretary may apply such timeframes and deadlines as the Secretary determines to be appropriate.

SEC. 406. LIMITATIONS ON CERTAIN ACTIVITIES AS PART OF HEALTH CARE OPERATIONS.

(a) MARKETING.—

(1) IN GENERAL.—A communication by a covered entity or business associate that is about a product or service and that encourages recipients of the communication to purchase or use the product or service shall not be considered a health care operation for purposes of subpart E of part 164 of title 45, Code of Federal Regulations, unless the communication is made as described in subparagraph (i), (ii), or (iii) of paragraph (1) of the definition of marketing in section 164.501 of such title.

(2) PAYMENT FOR CERTAIN COMMUNICATIONS.—Subject to subparagraph (B), a covered entity or business associate may not receive direct or indirect payment in exchange for making any communication described in subparagraph (i), (ii), or (iii) of paragraph (1) of the definition of marketing in section 164.501 of title 45, Code of Federal Regulations, except—

(A) a business associate of a covered entity may receive payment from the covered entity for making any such communication on behalf of the covered entity that is consistent with the written contract (or other written arrangement) described in section 164.502(e)(2) of such title between such business associate and covered entity; and

(B) a covered entity may receive payment in exchange for making any such communication if the entity obtains from the recipient of the communication, in accordance with section 164.508 of title 45, Code of Federal Regulations, a valid authorization (as described in paragraph (b) of such section), which shall be explicitly and affirmatively provided by the recipient, with respect to such communication.

(b) FUND RAISING.—Fundraising for the benefit of a covered entity shall not be considered a health care operation for purposes of section 164.501 of title 45, Code of Federal Regulations.

(c) EFFECTIVE DATE.—Subsections (a) and (b) shall apply to contracting occurring on or after the effective date specified under section 433.

(d) REGULATIONS.—

(1) IN GENERAL.—Not later than 18 months after the date of the enactment of this Act, the Secretary shall issue a notice of proposed rulemaking in the Federal Register, taking into account the report submitted under section 411 and the study under section 410, to eliminate from the definition of health care operations under section 164.501 of title 45, Code of Federal Regulations, those activities (other than the process of de-identifying health information) that can reasonably and efficiently be conducted through the use of information that is de-identified (in accordance with the requirements of section 164.514(b) of such title) or that should require a valid authorization for use or disclosure. In promulgating any such regulations, the Secretary may consider the form in which the health information is maintained, such as non-electronic records.

(2) CONSIDERATIONS.—In promulgating any such regulations, the Secretary shall take into consideration the extent to which—

(A) specific health care operations require the use or disclosure of protected health information; and

(B) clinical utility of such information would potentially be decreased in the case that

such information is de-identified or valid authorization is required; and

(C) the classification of health care operations (as in existence as of the date of the enactment of this Act) under section 164.501 of title 45, Code of Federal Regulations, may be further delineated.

SEC. 407. STUDY AND REPORT ON APPLICATION OF PRIVACY AND SECURITY REQUIREMENTS TO NON-HIPAA COVERED ENTITIES.

Not later than one year after the date of the enactment of this Act, the Secretary, in consultation with the Federal Trade Commission, shall conduct a study on privacy and security requirements to entities that are not considered covered entities as of the date of the enactment of this Act and submit to the Committee on Finance and the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Ways and Means and the Committee on Energy and Commerce of the House of Representatives a report on the findings of the study, including—

(1) requirements relating to security, privacy, and notification in the case of a breach of security or privacy (including the applicability of an exemption to notification in the case of individually identi-

fiable health information that has been rendered unusable, unreadable, or indecipherable through technologies or methodologies recognized by appropriate professional organization or standard setting bodies to provide effective security for the information) that should be applied to—

(A) vendors of personal health records;

(B) entities that offer products or services through the website of a vendor of personal health records;

(C) entities that are not covered entities and that offer products or services through the websites of covered entities that offer individuals personal health records;

(D) entities that are not covered entities and that access information in a personal health record or send information to a personal health record; and

(E) third party service providers used by a vendor or entity described in subparagraph (A), (B), (C), or (D) to assist in providing personal health record products or services;

(2) a determination of which Federal government agency is best equipped to enforce such requirements recommended to be applied to such ven-

dors, entities, and service providers under paragraph (1); and

(3) a timeframe for implementing regulations based on such findings.

SEC. 408. TEMPORARY BREACH NOTIFICATION REQUIREMENT FOR VENDORS OF PERSONAL HEALTH RECORDS AND OTHER NON-HIPAA COVERED ENTITIES.

(a) IN GENERAL.—In accordance with subsection (c), each vendor of personal health records, following the discovery of a breach of security of unsecured PHR identifiable health information that is in a personal health record maintained or offered by such vendor, and each entity described in subparagraph (B), (C), or (D) of section 407(1), following the discovery of a breach of security of such information that is obtained through a product or service provided by such entity, shall—

(1) notify each individual who is a citizen or resident of the United States whose unsecured PHR identifiable health information was acquired by an unauthorized person as a result of such a breach of security; and

(2) notify the Federal Trade Commission.

(b) NOTIFICATION BY THIRD PARTY SERVICE PROVIDERS.—A third party service provider that provides

services to a vendor of personal health records or to an entity described in subparagraph (B), (C), or (D) of section 407(1) in connection with the offering or maintenance of a personal health record or a related product or service and that accesses, maintains, retains, modifies, records, stores, destroys, or otherwise holds, uses, or discloses unsecured PHR identifiable health information in such a record as a result of such services shall, following the discovery of a breach of security of such information, notify such vendor or entity, respectively, of such breach. Such notice shall include the identification of each individual whose unsecured PHR identifiable health information has been, or is reasonably believed to have been, accessed, acquired, or disclosed during such breach.

(c) APPLICATION OF REQUIREMENTS FOR TIMELINESS, METHOD, AND CONTENT OF NOTIFICATIONS.—Subsections (c), (d), (e), and (f) of section 402 shall apply to a notification required under subsection (a) and a vendor of personal health records, an entity described in subsection (a) and a third party service provider described in subsection (b), with respect to a breach of security under subsection (a) of unsecured PHR identifiable health information in such records maintained or offered by such vendor, in a manner specified by the Federal Trade Commission.

(d) NOTIFICATION OF THE SECRETARY.—Upon receipt of a notification of a breach of security under subsection (a)(2), the Federal Trade Commission shall notify the Secretary of such breach.

(e) ENFORCEMENT.—A violation of subsection (a) or (b) shall be treated as an unfair and deceptive act or practice in violation of a regulation under section 18(a)(1)(B) of the Federal Trade Commission Act (15 U.S.C. 57a(a)(1)(B)) regarding unfair or deceptive acts or practices.

(f) DEFINITIONS.—For purposes of this section:

(1) BREACH OF SECURITY.—The term "breach of security" means, with respect to unsecured PHR identifiable health information of an individual in a personal health record, the acquisition, use, or disclosure of such information without the authorization of the individual.

(2) PHR IDENTIFIABLE HEALTH INFORMATION.—The term "PHR identifiable health information" means individually identifiable health information, as defined in section 1171(6) of the Social Security Act (42 U.S.C. 1320d(6)), and includes, with respect to an individual, information—

(A) that is provided by or on behalf of the individual; and

(B) that identifies the individual or with respect to which there is a reasonable basis to believe that the information can be used to identify the individual.

(3) UNSECURED PHR IDENTIFIABLE HEALTH INFORMATION.—

(A) IN GENERAL.—Subject to subparagraph (B), the term "unsecured PHR identifiable health information" means PHR identifiable health information that is not protected through the use of a technology or methodology specified by the Secretary in the guidance issued under section 402(h)(2).

(B) EXCEPTION IN CASE TIMELY GUIDANCE NOT ISSUED.—In the case that the Secretary does not issue guidance under section 402(h)(2) by the date specified in such section, for purposes of this section, the term "unsecured PHR identifiable health information" shall mean information that is not protected by technology standards developed or endorsed by a standards developing organization that is accredited by the American National Standards Institute.

(g) EFFECTIVE DATE; SUNSET.—

(1) IN GENERAL.—Subject to paragraph (2), the provisions of this section shall apply to breaches of security occurring during the period beginning on the date that is 90 days after the date of the enactment of this Act.

(2) SUNSET.—The provisions of this section shall not apply to breaches of security occurring on or after the earlier of the following:

(A) A standard relating to requirements for entities that are not covered entities that includes requirements relating to breach notification has been adopted by the Secretary under section 3002 of the Public Health Service Act, as added by section 101, and has taken effect.

(B) A standard relating to requirements for entities that are not covered entities that includes requirements relating to breach notification has been promulgated by the Federal Trade Commission and has taken effect.

SEC. 409. BUSINESS ASSOCIATE CONTRACTS REQUIRED FOR CERTAIN ENTITIES; OTHER PROVISIONS RELATED TO BUSINESS ASSOCIATE CONTRACTS.

(a) IN GENERAL.—Each organization, with respect to a covered entity, that provides data transmission of pro-

tected health information to such entity and that requires access on a routine basis to such protected health information, such as a Health Information Exchange, Regional Health Information Organization, or E-prescribing Gateway and each vendor of a personal health record that contracts with a covered entity for purposes of including a personal health record within an electronic medical record or electronic health record, is required to enter into a written contract (or other written arrangement) described in section 164.502(e)(2) of title 45, Code of Federal Regulations and a written contract (or other arrangement) described in section 164.308(b) of such title, with such entity and shall be treated as a business associate of the covered entity for purposes of the provisions of this title and subparts C and E of title 45, Code of Federal Regulations.

(b) COVERED ENTITIES TO MONITOR COMPLIANCE OF BUSINESS ASSOCIATES.—

(1) IN GENERAL.—A covered entity shall monitor the extent to which a business associate of such entity complies with the terms of the written contract (or other arrangement) described in section 164.502(e)(2) of title 45, Code of Federal Regulations or section 164. 308(b) of such title, as applicable, entered into between such entity and such business associate.

(2) ENFORCEMENT.—If in the process of investigating a complaint related to a violation of the requirements of this title or subpart C or E of title 45, Code of Federal Regulations, committed by a business associate of a covered entity, the Office for Civil Rights of the Department of Health and Human Services determines that—

(A) the covered entity reasonably should have known of a pattern of activity or practice of the business associate that was not in compliance with the terms of a contract described in paragraph (1) and that relates to such violation; and

(B) the covered entity did not take action required under section 164.504(e)(1)(ii) of title 45, Code of Federal Regulations in response to such pattern or practice,

the covered entity shall be treated, for purposes of section 1176 of the Social Security Act (42 U.S.C. 1320d–5), as having violated part C of title XI of such Act.

SEC. 410. GUIDANCE ON IMPLEMENTATION SPECIFICATION TO DE-IDENTIFY PROTECTED HEALTH INFORMATION.

Not later than 12 months after the date of the enactment of this Act, the Secretary shall, in consultation with stakeholders, issue guidance on how best to implement the requirements for the de-identification of protected health information under section 164.514(b) of title 45, Code of Federal Regulations.

SEC. 411. GAO REPORT ON TREATMENT, PAYMENT, AND HEALTH CARE OPERATIONS USES AND DISCLOSURES.

Not later than one year after the date of the enactment of this Act, the Comptroller General of the United States shall submit to the Committee on Finance and the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Ways and Means and the Committee on Energy and Commerce of the House of Representatives a report on—

(1) the best practices related to the disclosure among health care providers of protected health information of an individual for purposes of treatment of such individual, including an examination of the best practices implemented by States and by other entities, such as health information exchanges and regional health information organizations, and an

examination of the extent to which such best practices are successful with respect to the quality of the resulting health care provided to the individual and with respect to the ability of the health care provider to manage such best practices; and

(2) the best practices with respect to determining the minimum necessary set of protected health information for uses and disclosures of such information for purposes of payment and the most common health care operations, as specified by the Secretary, including those health care operations that could be reasonably and efficiently performed with either de-identified data (as defined in section 164.514(a) of title 45, Code of Federal Regulations) or the limited data set (as defined section 164.514(e)(1) of such title).

SEC. 412. CLARIFICATION OF APPLICATION OF WRONGFUL DISCLOSURES CRIMINAL PENALTIES.

Section 1177(a) of the Social Security Act (42 U.S.C. 1320d–6(a)) is amended by adding at the end the following new sentence: ''For purposes of the previous sentence, a person (including an employee or other individual who is not a covered entity, as defined in the HIPAA privacy regulation described in section 1180(b)(3)) shall be considered to have obtained or disclosed individually iden-

tifiable health information in violation of this part if the information is maintained by a covered entity (as so defined) and the person knowingly obtained or disclosed such information without authorization.''.

SEC. 413. IMPROVED ENFORCEMENT.

(a) IMPROVED CIVIL PENALTIES.—

(1) IN GENERAL.—Section 1176 of the Social Security Act (42 U.S.C. 1320d–5) is amended—

(A) in subsection (b)(1), by striking ''the act constitutes an offense punishable under section 1177'' and inserting ''a penalty has been imposed under section 1177 with respect to such act''; and

(B) by adding at the end the following new subsection:

''(c) NONCOMPLIANCE DUE TO WILLFUL NEGLECT.—

''(1) IN GENERAL.—A violation of a provision of this part due to willful neglect is a violation for which the Secretary is required to impose a penalty under subsection (a)(1).

''(2) REQUIRED INVESTIGATION.—For purposes of paragraph (1), the Secretary shall formally investigate any complaint of a violation of a provision of this part if a preliminary investigation of the facts

of the complaint indicate such a possible violation due to willful neglect.

"(3) REGULATIONS.—Not later than 90 days after the date of the enactment of the Health-e Information Technology Act of 2008, the Secretary shall issue a notice of proposed rulemaking in the Federal Register to implement this subsection.".

(2) EFFECTIVE DATE.—The amendments made by paragraph (1) shall apply to penalties imposed on or after the date specified in section 433.

(b) DISTRIBUTION OF CIVIL MONETARY PENALTIES COLLECTED.—

(1) IN GENERAL.—Subject to the regulation promulgated pursuant to paragraph (3), any civil monetary penalty collected with respect to an offense punishable under this title or section 1176 of the Social Security Act (42 U.S.C. 1320d–5) shall be transferred to the Office of Civil Rights of the Department of Health and Human Services to be used for purposes of enforcing the provisions of this title and subparts C and E of title 45, Code of Federal Regulations.

(2) GAO REPORT.—Not later than 18 months after the date of the enactment of this Act, the Comptroller General shall submit to the Secretary a

report including recommendations for a methodology under which an individual who is harmed by an act that constitutes an offense punishable under this title or section 1176 of the Social Security Act may receive a percentage of any civil monetary penalty collected with respect to such offense under this title or such section.

(3) ESTABLISHMENT OF METHODOLOGY TO DISTRIBUTE PERCENTAGE OF CMPS COLLECTED TO HARMED INDIVIDUALS.—Not later 3 years after the date of the enactment of this Act, the Secretary shall establish by regulation and based on the recommendations submitted under paragraph (2), a methodology under which an individual who is harmed by an act that constitutes an offense punishable under this title or section 1176 of the Social Security Act may receive a percentage of any civil monetary penalty collected with respect to such offense under this title or such section.

(4) APPLICATION OF METHODOLOGY.—The methodology under paragraph (3) shall be applied with respect to civil monetary penalties imposed on or after the effective date of the regulation.

(c) TIERED INCREASE IN AMOUNT OF CIVIL MONETARY PENALTIES.—

(1) IN GENERAL.—Section 1176(a)(1) of the Social Security Act (42 U.S.C. 1320d–5(a)(1)) is amended by striking "who violates a provision of this part a penalty of not more than" and all that follows and inserting the following: "who violates a provision of this part—

"(A) in the case of a violation of such provision in which it is established to the satisfaction of the Secretary that the person did not know (and by exercising reasonable diligence would not have known) that such person violated such provision, a penalty for each such violation of an amount that is at least the amount described in paragraph (3)(A) but not to exceed the amount described in paragraph (3)(D);

"(B) in the case of a violation of such provision in which it is established to the satisfaction of the Secretary that the violation was due to reasonable cause and not to willful neglect, a penalty for each such violation of an amount that is at least the amount described in paragraph (3)(B) but not to exceed the amount described in paragraph (3)(D); and

"(C) in the case of a violation of such provision in which it is established to the satisfaction of the Secretary that the violation was due to willful neglect—

"(i) if the violation is corrected as described in subsection (b)(3)(A), a penalty in an amount that is at least the amount described in paragraph (3)(C) but not to exceed the amount described in paragraph (3)(D); and

"(ii) if the violation is not corrected as described in such subsection, a penalty in an amount that is at least the amount described in paragraph (3)(D).

In determining the amount of a penalty under this section for a violation, the Secretary shall base such determination on the nature and extent of the violation and the nature and extent of the harm resulting from such violation.".

(2) TIERS OF PENALTIES DESCRIBED.—Section 1176(a) of such Act (42 U.S.C. 1320d–5(a)) is further amended by adding at the end the following new paragraph:

"(3) TIERS OF PENALTIES DESCRIBED.—For purposes of paragraph (1), with respect to a violation by a person of a provision of this part—

"(A) the amount described in this subparagraph is $100 for each such violation, except that the total amount imposed on the person for all such violations of an identical requirement or prohibition during a calendar year may not exceed $25,000;

"(B) the amount described in this subparagraph is $1,000 for each such violation, except that the total amount imposed on the person for all such violations of an identical requirement or prohibition during a calendar year may not exceed $100,000;

"(C) the amount described in this subparagraph is $10,000 for each such violation, except that the total amount imposed on the person for all such violations of an identical requirement or prohibition during a calendar year may not exceed $250,000; and

"(D) the amount described in this subparagraph is $50,000 for each such violation, except that the total amount imposed on the person for all such violations of an identical re-

quirement or prohibition during a calendar year may not exceed $1,500,000.''.

(3) CONFORMING AMENDMENTS.—Section 1176(b) of such Act (42 U.S.C. 1320d–5(b)) is amended—

(A) by striking paragraph (2) and redesignating paragraphs (3) and (4) as paragraphs (2) and (3), respectively; and

(B) in paragraph (3)—

(i) in subparagraph (A), by striking ''in subparagraph (B), a penalty may not be imposed under subsection (a) if'' and all that follows through ''the failure to comply is corrected'' and inserting ''in subparagraph (B) or subsection (a)(1)(C), a penalty may not be imposed under subsection (a) if the failure to comply is corrected''; and

(ii) in subparagraph (B), by striking ''(A)(ii)'' each place it appears and inserting ''(A)''.

(4) EFFECTIVE DATE.—The amendments made by this subsection shall apply to violations occurring after the date of the enactment of this Act.

(d) ENFORCEMENT BY STATE ATTORNEYS GENERAL.—

(1) CIVIL ACTIONS.—In any case in which the attorney general of a State or any State or local law enforcement agency authorized by the State attorney general or by State law to prosecute violations of consumer protection laws, has reason to believe that an interest of the residents of that State has been or is threatened or adversely affected by the engagement of a person in a practice that is prohibited under a provision of this title or subparts C or E of title 45, Code of Federal Regulations, the State or local law enforcement agency on behalf of the residents of the agency's jurisdiction, may bring a civil action on behalf of the residents of the State or jurisdiction in a district court of the United States of appropriate jurisdiction to—

(A) enjoin that act or practice;

(B) enforce compliance with the provision; or

(C) obtain civil penalties in an amount calculated by multiplying the number of violations by an amount not greater than $11,000.

(2) RULE OF CONSTRUCTION.—For purposes of bringing any civil action under paragraph (1), noth-

ing in this title regarding notification shall be construed to prevent an attorney general of a State from exercising the powers conferred on such attorney general by the laws of that State to—

(A) conduct investigations;

(B) administer oaths or affirmations; or

(C) compel the attendance of witnesses or the production of documentary and other evidence.

(3) VENUE; SERVICE OF PROCESS.—

(A) VENUE.—Any action brought under paragraph (1) may be brought in the district court of the United States that meets applicable requirements relating to venue under section 1391 of title 28, United States Code.

(B) SERVICE OF PROCESS.—In an action brought under paragraph (1), process may be served in any district in which the defendant—

(i) is an inhabitant; or

(ii) may be found.

SEC. 414. AUDITS.

The Secretary shall provide for periodic audits to ensure that entities that are subject to the requirements of this title and subparts C and E of title 45, Code of Federal Regulations, comply with such requirements.

SEC. 415. TECHNICAL AMENDMENT.

Section 1171(5) of the Social Security Act (42 U.S.C. 1320d) is amended by striking "or C" and inserting "C, or D".

Subtitle B—Chief Privacy Officer of ONCHIT; Standards and Guidance Recommendations Related to Privacy and Security

SEC. 421. CHIEF PRIVACY OFFICER OF THE OFFICE OF THE NATIONAL COORDINATOR .

(a) IN GENERAL.—To assist the National Coordinator in carrying out all the duties of the National Coordinator relating to the privacy and security of health information, not later than 12 months after the date of the enactment of this Act, the Secretary shall appoint a Chief Privacy Officer of the Office of the National Coordinator established under section 3001(a) of the Public Health Service Act, as added by section 101.

(b) CONSULTATION.—In carrying out the duties under subsection (a), the Chief Privacy Officer shall consult with the officials designated under subsection (c)(1) and is encouraged to consult with officials in other Federal agencies who have primary responsibility relating to the privacy and security of individually identifiable information.

(c) COORDINATION WITH INTERNAL PRIVACY OFFICERS.—The Secretary shall ensure that—

(1) not later than 12 months after the date of the enactment of this Act, each agency specified by the Secretary with the Department of Health and Human Services that deals with health information has an official who is designated with specific responsibilities with regard to the privacy and security of such information; and

(2) such officials coordinate their activities with the Chief Privacy Officer.

SEC. 422. ADDITIONAL STANDARDS AND GUIDANCE RECOMMENDATIONS RELATED TO PRIVACY AND SECURITY.

(a) IN GENERAL.—In carrying out section 3001(c)(2) of the Public Health Service Act, as added by section 101, the National Coordinator shall—

(1) periodically recommend to the Secretary standards and guidance related to ensuring the privacy and security of health information for purposes of adoption under section 3003(a) of such Act, as so added; and

(2) periodically review and revise as necessary health information privacy and security standards and regulations implemented under this title and

subparts C and E of title 45, Code of Federal Regulations.

(b) SPECIFIC RECOMMENDATIONS.—For purposes of subsection (a), the National Coordinator shall submit to the Secretary recommendations on at least the following:

(1) APPLICATION OF HIPAA TO ENTITIES THAT AREN'T COVERED ENTITIES.—Taking into account the results of the study conducted under section 407, recommendations—

(A) on the extent to which the provisions of this title and subparts C and E of title 45, Code of Federal Regulations, should apply to entities using, disclosing or receiving health information that are not included under this title or such subparts as a covered entity or business associate; and

(B) that identify to which entities that are not so included should such provisions apply.

(2) COLLECTION LIMITATIONS.—Recommendations identifying under what circumstances and for what purposes protected health information may be collected, including model notices for such purposes as necessary and recommendations about which of such purposes should require separate, prior author-

ization from the individual involved. Such recommendations shall provide that—

(A) such collection will occur in a transparent process;

(B) such collection shall be in accordance with applicable Federal, State, and local laws; and

(C) such collection may only occur for the purposes specified by the entity collecting the information and such purposes must be so specified at least not later than the time of collection.

(3) DISCLOSURE AND USE LIMITATIONS.—Recommendations identifying the circumstances under which, to whom, and for what purposes protected health information may be used or disclosed, including—

(A) recommendations about what uses or purposes are permitted or required (taking into account that protected health information shall be disclosed in a non-identifiable manner to the maximum extent possible);

(B) recommendations on best practices on de-identifying data;

(C) recommendations for a technical standard that allows for the de-identification of health information;

(D) recommendations on how to segregate sensitive protected health information with the goal of minimizing the reluctance of patients to seek care (or disclose information about a condition) because of privacy concerns involving sensitive protected health information while maximizing patient safety and clinical utility of the information;

(E) recommendations to define the "minimum necessary" set of health information for the most common treatment and health care operations, as specified by the Secretary; and

(F) recommendations for standardized notification describing, in terms that are easily understandable to individuals, permissible uses and disclosures for the most common payment and health care operations purposes and specific to the most common covered entities.

(4) ELECTRONIC HEALTH RECORDS AND ELECTRONIC MEDICAL RECORDS SECURITY FEATURES.—Recommendations on security features, such as user authentication, identity management tools, and data

scrubbing, that electronic health records must have in order to receive certification under the program under section 3001(c)(3) of the Public Health Service Act, as added by section 101. Such recommendations shall include at a minimum recommendations with respect to immutable audit trails.

(5) DATA ACCURACY.—Recommendations on how to maximize the accuracy of health information used or disclosed.

(6) ACCOUNTABILITY.—Recommendations on how to best provide for accountability for uses and disclosures of health information.

(7) TRANSPARENCY.—Recommendations on how to maximize the transparency and openness of health information privacy and security policies, including requiring that notices informing individuals of such policies be written in an understandable and simple manner and clearly and simply describe what the privacy and security policies are and how individuals can access their protected health information and amend it.

(8) ENFORCEMENT.—Recommendation on how to improve and revise the enforcement of this title and subparts C and E of title 45, Code of Federal Regulations.

(9) REDUCTIONS IN BREACHES.—Recommendations on how to reduce the number and scope of breaches, taking into account information received by the Secretary under section 3002(e)(3) of the Public Health Service Act.

The National Coordinator shall, to the maximum extent practicable, include the recommendations described in paragraphs (1), (3)(C), (3)(D), and (4) in the initial set of recommendations submitted by the Coordinator under section 3001(c)(2)(A) of the Public Health Service Act, as added by section 101.

Subtitle C—Relationship to Other Laws; Regulatory References; Effective Date

SEC. 431. RELATIONSHIP TO OTHER LAWS.

(a) APPLICATION OF HIPAA STATE PREEMPTION.—Section 1178 of the Social Security Act (42 U.S.C. 1320d–7) shall apply to a provision or requirement under this title in the same manner that such section applies to a provision or requirement under part C of title XI of such Act or a standard or implementation specification adopted or established under sections 1172 through 1174 of such Act.

(b) HEALTH INSURANCE PORTABILITY AND ACCOUNTABILITY ACT.—The standards governing the pri-

vacy and security of individually identifiable health information promulgated by the Secretary under sections 262(a) and 264 of the Health Insurance Portability and Accountability Act of 1996 shall remain in effect to the extent that they are consistent with this title. The Secretary shall by rule amend such Federal regulations as required to make such regulations consistent with this title.

SEC. 432. REGULATORY REFERENCES.

Each reference in this title to a provision of the Code of Federal Regulations refers to such provision as in effect on the date of the enactment of this Act (or to the most recent update of such provision).

SEC. 433. EFFECTIVE DATE.

The provisions of subtitles A and B of this title (other than sections 401(c), 402, 403, 405(c), 405(d), 406(d), 407, 408, 410, 411, 412, 413(b)(2), 413(b)(3), 413(c), 415, 421, 422, 431, and 432) shall take effect on the date that is 12 months after the date of the enactment of this Act.

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